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June 4, 2004

By E-MAIL and By FedEx
June 6, 2004 June 4th

(Docket # 2004Q-0151) - Solae Corporation Requests Health Claim, re: Qualified Health Claim: Soy Protein and Cancer
(Suggesting the consumption of soy protein-based foods may reduce the risk of certain types of cancers including breast, prostate and colon cancer.)

Dear Ms Anderson,

In submitting this petition for filing our **objection** to Solae Corporation's application for a Qualified Health Claim for Soy Protein and Cancer, (see Docket Number above), we would like you and your staff in the FDA to seriously consider this submission with the following collection of 61 scientific research abstracts, **(the evidence)**, out of a continually growing list of hundreds available, that represents a fast growing body of scientifically creditable medical and dietary research on the many serious health hazards, including cancer, from putting soy in our food supply. (Personally, we have collected over 200 abstracts documenting the harmful side-effects of eating soy, and thi collection of ours represents only some of those available in the scientific community, world wide.). All abstracts presented here are also published in the NIH Medline data base and are representative of current and past research from around the world, in 2004 and going back to 1953, even as far back as 1925. The full research is also available via these abstracts. Notice that some of the research studies included with this petition are from the US Department of Energy and NCTR which are Federally operated and funded, and other very reputable research institutions from around the world.

You will be able to see from the scientific research, the evidence, which includes but is not limited to the evidence in this petition of objection to Solae Corporation's request for a "Qualified Health Claim," that the research is from well-designed studies, from around the world, conducted in a manner which is consistent with generally recognized scientific procedures and principles which show that **there does exist** significant scientific agreement among experts qualified by scientific training and experience, from around the world, a very strong statistically significant association of harm to human and animal health from the consumption of soy and soy protein ingredients in our food supply and **an INCREASED RISK of a variety of cancers and other major and life threatening health problems, referred to in this submission as "Hidden Harm,"** which includes but is not limited to breast cancer, prostate cancer, increased cancer cell proliferation, tumor growth, DNA and chromosome damage, immune system damage-(including T-cell production, activity), DNA double strand breaks, thyroid damage and thyroid cancer, and damage to the myelin sheath surrounding the nerves. .

In this, our petition of objection, we will also point out, what are in our opinion, based on publically known facts, several serious errors, flaws, misrepresentations, in Solae Corporation's application requesting a Qualified Health Claim for Soy Protein and Cancer. Since the Solae Corporation is newly formed in around April of 2003, less than a year before they made their application to the FDA this year, 2004, I would expect that their lack experience and knowledge would mostly, but not completely, accounts for these errors, misrepresentation(s) of the facts in their application to the FDA, as well as, their narrow focus on their selection of research, (from that which is easily and widely available world wide), used in trying to justify and prove their flawed argument for a Qualified Health Claim for Soy and Cancer.

Petition of Objection To
(Docket # 2004Q-0151) - Solae Corporation requests FDA Health Claim
re: Qualified Health Claim: Soy Protein May Reduce Risk Of Cancer

This long known and ignored and now denied **"evidence"** of the **"Hidden Harm"** from the many serious and sometimes deadly health hazards to human and animal health from the naturally occurring toxic ingredients in soy, **genistein**, **daidzein**, and **beta-Sitosterol**, is research done in both vivo and in vitro. **Beta-Sitosterol is a compound common in soy oil, and also present in soy protein.** We feel that this **"evidence"** documenting the many serious health hazards from eating soy in important news to everyone, information that the average person needs to know, but has not been told, information even withheld from the general public, we feel as censored through denial by the soy industry, FDA, Health Canada, the news media in general, and most governments around the world. Yet this information has been long known and ignored for all these years by the soy industry, new media, authors of many well know books on nutrition, the food industry, the health food industry, the FDA, American and Canadian Cancer Societies, the mainstream medical system, the alternative health system, Naturopaths, and many government departments in most countries around the world, in a manner similar to they way the ...

1.) knowledge of the health hazards of smoking was kept from people 30 - 50 years ago, and
2.) knowledge of the health hazards of HRT, estrogens, was kept from people for over 30 years prior to 2002,
3.) and the present way Monsanto keeps the "Hidden Danger in Your Milk from BGH growth hormone,", still is secret and censored in the news media today, see ... http://www.foxBGHsuit.com and http://www.thecorporation.tv/about/ .

We all know that the goal of the soy industry, like all businesses, is to move product, to sell more and more product, but it shouldn't be at the expense of the health of people and animals, as it is today. When it is, then making money is all about the profit motivation, making money at the expense of the public good, peoples health, rather than along with the health, safety and well being of the customer. Why should any one be forced to take risks to their personal health from soy ingredients in the food they eat, like Soy Protein Isolate, SPI, when the individual has not been made aware of the dangers, in order for them to exercise their choice to eat soy or not ??. Those who manfacture and sell soy products, ingredients have not received "informed consent" from the general population, from anyone exposed to these hazards from eating soy. Informed consent from issuing a **Health Protection Advisory, or a Public Health Warning** about these **"Hidden Dangers."** We all have the "Right to Know," first, to make an "Informed Choice" if they are willing to be exposed to the health hazards of eating soy ingredients in their food. Everyone has the right not be experimented on, used as "Guinea Pigs" according to the **"Declaration of Helsinki"** and the **"Nuremberg Code "**. According to international agreement and law, this kind of choice should have been, and should be, made available to everyone all these past years, especially cancer patients, women, pregnant women, children and the elderly. Is there any accountability in government and the food industry??. Since we all have the "Right to Know," this is where you, the FDA, can start to put a stop to this harm to our health from soy ingredients in our food supply. Isn't it the roll of the FDA to protect the citizens it represents ??, or is it to protect and further the financial interest of the business world, the corporations, at the expense of the safety and well-being of the citizens the FDA represents and is supposed to protect ??. You know the old saying, "Safety starts at the top, Safety is no accident."

Soy has always been a serious health hazard and nothing has changed that over the past several thousand years, even the westernized processing of soy does not remove these health hazards, but also adds more, adds to the toxic, poisonous, cancer causing ingredients to soy, along with their harmful side-effects. These harmful side-effects are pointed out on the next page and are supported with current and past scientific research. We also feel that the FDA should not allow the soy industry to self-regulate itself by allowing them GRAS Self Determination.

Because of the strong evidence coming from the research scientists own studies, many researchs feel it necessary, feel that it is "The Right Thing To Do" ... The Humanitarian Thing To Do" ... "The Ethical Thing To Do" ... to inform people, to give people a chance and a choice to protect themselves and the ones they love from danger by giving cautions and warning in their abstracts about eating soy and soy ingredients and soy supplements.

* Note - When pharmaceutical companies advertise their drugs in TV commercials, these TV commercials are required to notify, warn, the general public watching of the negative side-effects, of the adverse medical health hazards they may experience from taking the drug being advertised. There is no such warning to consumers about the many serious and sometimes deadly health hazards from soy and ingredients in our foods supply. This is in contravention of the laws in many countries requiring **informed consent** from the consumer, as in Canada and the USA. See the list of the many health hazards below

Here are some examples of the cautions and warning you will find in this collection of abstracts in this submission, alerting people to the fact that soy and soy ingredients like soy protein isolate, SPI, genistein and diadzein and beta-sitosterol most definitely do cause cancer cells and tumors to grow, in vivo and in vitro ...

Page 29

— "Therefore, **caution is warranted** for postmenopausal women consuming dietary genistein while on TAM therapy for E-responsive breast cancer."

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— Women with current or past breast cancer "should be aware of the "risks" of potential tumor growth" when taking soy products.

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— women with estrogen-dependent brest cancer or predisposition to it may want to reduce their consumption of soy products with a high isoflavone content.

— In the paper in Carcinogenesis, the researchers compared the isoflavone in its two forms, as a glycoside (genistin, as it appears in plants) and aglucone (genistein). They found that both forms produced similar tumor growth rates, and that the conversion of genistin in the body begins with contact with saliva in the mouth.

— In Cancer Research, Helferich compared soy protein isolates containing varying levels of isoflavones.

— researchers found that estrogen-dependent tumor growth increases as the isoflavone content increased in the soy-containing diet.

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— Breast cancer is one of the most common forms of cancer observed in women, and endogenous estrogen is thought to play a major role in its development.

— Because of this, any conditions or exposures which enhance estrogenic responses would result in an increased risk for breast cancer.

page 39

— The proliferation rate of breast lobular epithelium ... significantly increased ... after just 14 days ... of soy supplementation ... when both the day of menstrual cycle & age of patient were accounted for. Thus short-term use of dietary soy containing isoflavone levels found in modern soy foods stimulates breast proliferation.

— Genistein causes Proliferation of cultured human breast cancer cells ... Dees concluded that ' women should not consume particular foods, (eg. soy-derived products), to prevent breast cancer'.

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— A study with (24) normal pre- and post- menopausal white women, ages 30 - 58 were studied for one year.

— The authors noted that "the findings did not support our a priori hypothesis" that soy protected Asian women against breast cancer.

— "Instead, this pilot study indicates that "prolonged consumption" of soy protein isolate has a "stimulatory effect" on the premenopausal female breast ... genistein and daidzein in Soy protein isolate (SPI).

So to try and bend the scientific evidence to try to make it fit what the soy industry and the pharmaceutical companies want it to look like, that soy supposedly prevents cancer, is doing the same thing the pharmaceutical companies did for over 20 years before June 2002, when the studies on Hormone Replacement Therapy, HRT, were stopped because these studies were proving that HRT was causing the very illness in women, including cancer, that the pharmaceutical companies were claiming and saying that HRT prevented.

What are some of these growing number of serious side-effects from eating soy and Soy Protein Isolate, SPI ??. They are listed on the next page under the heading **"Hidden Harm."** The abstracts, scientific evidence, proving this is at the end of this submission, showing how soy damages human and animal health , while clearly documenting these known and ignored cancer risks to consumers from the Solae (and other) soy products. These health hazards are well known to much of the general scientific community, but ignored and suppressed, even denied by the soy industry, their scientists, the news media, the mainstream medical system, the natural health industry, the alternative health system, American and Canadian Cancer Societies, and many government departments from around the world like the FDA and Health Canada, and from those making their living from producing, promoting and selling soy and soy ingredients like soy protein isolate, SPI.

"The Hidden Harm" that is done to people from putting soy and soy ingredients into our food supply without notifying and informing people of these many harmful side-effects to health is listed below. While reading this list of just some of the harmful side-effects from eating soy and soy ingredients in our food, keep in mind that Genistein in soy is a dietary topoisomerase II-poison, it accumulates in the body over time, building up a toxic load over time and is one of the cause of the medical problems listed below. Also keep in mind that because of this, genistein causes **DNA double strand breaks** leading to, among other things, **chromosomal aberrations and leukemia's, like acute infant leukemia, AIL, otherwise known as Cancers of different types.**

The negative health risks of soy in our food supply clearly far out weighs any imagined benefits to health.

"Hidden Harm"

No Health Protection Advisory, No Public Health Warnings
The many harmful side-effects to human and animal
health from putting soy in our food supply.
Known, Ignored, Denied
?

Although this petition of objection to Solae's application for "Qualified Health Claim for Soy and Cancer Prevention" is primarily focusing on cancer, breast cancer and damage to the immune system and DNA damage, many other scientifically documented, yet ignored, health hazards from eating soy also include but are not limited to those in the list below...

... Asthma
... Brain and Nervous System damage -
(genistein destroys myelin sheath protecting nerves,
as in "Alzheimer's and Parkinson's disease",
and learning disabilities as in ADD/ADHD)
... Cancer(s) / Breast / liver / uterine / colon / thyroid / pancreas / thyroid
... Causing the Reoccurrence of cancer(s).
... Cell *DEATH* , animal *DEATHs*, and human *DEATHs*
... Chronic fatigue
... Chromosome fragmentation, and errors in its orientation
... DNA damage
... Diabetes
... Depression , Dementia
... Endocrine disruption
... Growth problems
... Heart disease , arrhythmia
... Irritable Bowl Syndrome
... Liver disease
... Leukemia, infantile acute leukemia, (IAL)
... Infertility and reproductive problems
... Osteoporosis
... Premature, delayed puberty, Pseudo-Puberty
... Pancreatic disorders
... Thyroid suppression, Goiter,
Hyper and Hypo-thyroidism
Graves' or Hashimoto's Disease
... Immune system suppression - including
(suppression of T-cell production, activity)
... Subtle changes in sexually dimorphic behaviors
... Weight gain

... Genistein in soy is a dietary topoisomerase II-poison, it accumulates in the body over time, building up a toxic load and causes **DNA double strand breaks** leading to **chromosomal aberrations and leukemia's, like AIL.**

Pregnant women and their unborn child are at great risk of harm from soy ingredients in our food supply. The toxic ingredient in soy genistein crosses the placenta and blood-brain barrier, "teratogenic," causing birth defects, as test have shown. The placenta does not represent a barrier to these poisons. Children, especially children – who in some instances may be affected by soy products consumed either by themselves (for instance, in baby formula) or by their mothers prior to giving birth need to be protected from these health hazards. Infants are the most vulnerable and defenseless individuals of our society. Also, see abstracts in reference section below and at the end.

The negative health risks of soy in our food supply clearly far out weighs any imagined benefits to health.

The metabolism, physiology and biochemistry of a ... fetus ... infant ... or child ... is fundamentally different from that of an adult. A host of vital organ systems continue to grow and mature from conception throughout childhood. At critical periods of developmental change, these systems are susceptible to the toxic effects of pesticides and toxic chemicals, both individually and "in mixtures." Many organ systems, for example the nervous system and brain, can be permanently, and subtly damaged by exposures to toxic substances in-utero or throughout early childhood that, at the same level, cause no measurable harm to adults **(Jacobson 1996, CDC 1997, NRC 2000).**

The endocrine (hormone) system , (immune system), is perhaps even more sensitive to toxic exposure than the nervous system, and over the past decade, enormous effort has been put into the study of how pesticides and toxic chemicals interfere with normal endocrine signaling and function.

A significant body of research in animals now shows that ... "ultra-low doses" ... toxic chemicals on critical days of development can cause changes in hormone function and effects on organ development and function that often only appear later in life. A growing number of these studies show that low doses at a susceptible moment of development can cause **more** of an effect than high doses **(vom Saal 1997, Alworth 2002, Hayes 2003.** This is particularly relevant to childhood and fetal exposures via food & water where the timing of the exposure is at least as important as dose.

The use of the Precautionary Principle at ... http://www.biotech-info.net/rachels_586.html says that people have a duty to take anticipatory action to prevent harm, have an obligation to try to stop it. This includes those in the FDA at the decision making level to not allow Solae Company's application. The FDA has more than a reasonable suspicion from scientific proof, (including but not limited to what is presented here), that something bad might be and will be going to happen, when soy and soy ingredients like Soy Protein Isolate, SPI, is added to our food supply and the FDA has an obligation to try to stop it. Not at sometime in the future, but now. Why ??. Because FDA knows of the **"Hidden Harm"** people are currently experiencing from soy ingredients in our food supply. If they claim they do not, then they sure do after reading this submission. The Precautionary Principle is not really New. It is captured in common-sense aphorisms down throughout history, such as "An ounce of prevention is worth a pound of cure" ... "Better safe than sorry" ... "Look before you leap" ... "Error on the side of caution" ... etc., etc.

When talking about Social Justice, Socrates said about "Courage," ... "Examine your thoughts, statements and actions by pursuing their implications, on the assumption that if they are true, they would not lead to false consequences," and about ... "Humanitarian Action" ... "Choose wisdom so that society is incapable of doing wrong."

The American College Dictionary, 1964 , definition of "Ethics" ... n. pl. 1.) The principles of morality, including both the science of the good and the science of right.

U.S. food safety law has mandated the precautionary approach since 1958. In that year, Congress passed the Food Additive Amendment to the Food, Drug and Cosmetic Act requiring that new additives to food be demonstrated safe through standard scientific testing before they are marketed. (21 U.S.C. Sec. 321). Those in the FDA in positions of authority and in the decision making process to approve or reject Solae's application know that US laws requires that soy and soy ingredients must be proven safe. ***US Law Mandates Rigorous Application of the Precautionary Principle.***

An official Senate report described the intent of the amendment (21 U.S.C. Sec. 321) as follows: "While Congress did not want to unnecessarily stifle technological advances, it nevertheless intended that additives created through new technologies be proven safe before they go to market. S. Rep. 2422, 1958 U.S.C.C.A.N. 5301-2. (emphasis added) This clearly shows that the precautionary principle is the cornerstone of food safety law in the United States.

As both the FDA's regulations and the federal courts have decreed, general recognition of safety can only be imputed if there is an overwhelming consensus in the community of qualified experts. While unanimity is not required, any significant and sound disagreement prevents a determination that consensus exists.

To approve a Qualified Health Claim for soy as Solae requests the FDA to do would be breaking the law and misrepresenting the dangerous facts.

The requisite consensus for Soy has never existed, and the FDA is well aware of it because the predominant consensus among its own experts was that these soy ingredients entail unique risks and cannot be presumed safe. The pervasiveness of concern within the FDA's scientific staff is attested by the 2 FDA whistle blower stated : ... Researchers and "Whistle-blowers" Daniel Doerge Ph.D and Daniel Sheehan Ph.D are two of the U.S.A.'s Food and Drug Administration's, FDA, expert scientists on soy who signed a Feb. 18, 1999 letter of protest to the FDA when the FDA granted soy a "health claim" in 1999. This letter expresses serious concerns regarding the perceived safe use of soy, if soy was to be granted a "health claim," and includes 26 documented scientific referenced studies, (Abstracts), that show a link between eating soy and serious health problems.

In their letter of protest they said,

"… it is inappropriate to allow a health claim for Soy Protein Isolate, SPI, … it could be misinterpreted, … the health labeling of SPI for foods needs to be considered just as would the addition of any "Estrogen" or "Goitrogen" to foods, which are bad ideas. Estrogenic and goitrogenic drugs are regulated by the FDA, and are taken under a physician's care. Patients are informed of risks, and are monitored by their physicians for evidence of toxicity. No similar safeguards are in place for foods, so the public will be put at potential risk from soy isoflavones in SPI without adequate warning and information..."

See letter ... http://abcnews.go.com/onair/2020/2020_000609_soyfdaletter_feature.html, **article withdrawn**,
and at ... http://health.groups.yahoo.com/group/hypothyroidism/message/7065 , **Use Google Search for more.**

But even in the case of unanimity, U.S. law additionally prescribes that consensus cannot rest on hypotheses but must be based on scientific evidence that clearly establishes safety. Both the FDA's regulations and the federal courts have consistently held that such evidence should include studies published in the peer-reviewed scientific literature. (21 CFR Sec. 170.3(h)). Moreover, FDA regulations emphasize that the tests supporting a general recognition of safety "...require the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive." (21 CFR Sec. 170.30(b)) This means, in the FDA's words, that the tests must demonstrate "a reasonable certainty ... that the substance is not harmful under its intended conditions of use." (21 CFR Sec. 170.3(I)). Therefore, even if expert consensus about the safety of soy and soy ingredients actually existed, which it doesn't, the law requires that their safety still must be established through standard scientific tests.

The short list of abstracts in the reference section, shows that it is very well documented scientifically that soy causes a variety of very serious adverse medical and developmental conditions in susceptible persons, like various types of cancers.

The science very clearly establishes that soy is not medically necessary, but there is a medical necessary to warn people of these serious health hazards so people can then choose to avoid soy and soy ingredients in our food supply for disease prevention and for maintaining good health.

In fact, in the next **1998** abstract below, being the **1st abstract** presented for your consideration, it is stated in a meta-analysis done then by ***Strauss L., Santti R., Saarinen N., Streng T., Joshi S., and Makela S.,*** at the **Institute of Biomedicine and Medicity Research Laboratory, University of Turku, Finland**, found that

> "... there is no direct evidence for the beneficial effects of phytoestrogens in humans. ... All information is based on consumption of phytoestrogen-rich diets, and the causal relationship and the mechanisms of phytoestrogen action in humans still remain to be demonstrated ... In addition, the possible adverse effects of phytoestrogens have not been evaluated ... It is plausible that phytoestrogens, as any exogenous hormonally active agent, might also cause adverse effects in the endocrine system, i.e. act as endocrine disrupters ...".

Since 1998, there is still no direct medical evidence proving the need for soy in our food supply, nothing has changed and this is still exactly the case today as it was back in 1998. This fact is part of the reason why Solae says twice on pages 115 and 116 in their application for a Qualified Health Claim, which is discussed in the 3rd point of this submission, that "...However, this, Solae's, evidence is not conclusive..." for their request for a Qualified Health Claim of Soy and Cancer Prevention.. To attempt to knowing endanger the public's health to scientifically known health hazards by submitting evidence that is not conclusive, is, I suggest, a criminal act of global proportions, as is explained in quite legal detail further on in this submission.

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10022277&dopt=Abstract .
Toxicol Lett. 1998 Dec 28;102-103:349-54.

1998 "Dietary phytoestrogens and their role in hormonally dependent disease," — *Strauss L., Santti R., Saarinen N., Streng T., Joshi S., Makela S.,* Institute of Biomedicine and Medicity Research Laboratory, University of Turku, Finland.

> – Although epidemiological studies suggest that diets rich in phytoestrogens may be associated with low risk of breast and prostate cancer, **there is no direct evidence for the beneficial effects of phytoestrogens in humans.** It is plausible that phytoestrogens, as any exogenous hormonally active agent, might also cause adverse effects in the endocrine system.
> **– Epidemiological studies suggest that diets rich in phytoestrogens (plant estrogens), particularly soy and unrefined grain products, may be associated with low risk of breast and prostate cancer.** It has also been proposed that dietary phytoestrogens could play a role in the prevention of other estrogen-related conditions, namely cardiovascular disease, menopausal symptoms and post-menopausal osteoporosis.
> – However, there is no direct evidence for the beneficial effects of phytoestrogens in humans.
> – All information is based on consumption of phytoestrogen-rich diets, and the causal relationship and the mechanisms of phytoestrogen action in humans still remain to be demonstrated.
> – In addition, the possible adverse effects of phytoestrogens have not been evaluated.
> – It is plausible that phytoestrogens, as any exogenous hormonally active agent, might also cause adverse effects in the endocrine system, i.e. act as endocrine disrupters.

Again, in 2003, The United Kingdom Chief Medical Officer, the highest medical officer in the UK has issued a "Health Protection Advisory" about the long term reproductive harm to children from soy protein. He has drawn on the findings of at least four expert committees, going back to July 1996. In his Health Protection Advisory," he has warned all doctors that ...

> ... soy - based infant formulas should be used only in exceptional circumstances, because of "... a risk to long term reproductive health ...".

Further information on the UK Expert Committee's findings in a report in March **2003** called "Committee on Toxicity of Chemicals in Food, Consumer Products and The Environment, Report on Phtoestrogens and Health," is at ... http://www.food.gov.uk/multimedia/pdfs/2003-03.pdf , and also says ...

> "... After reviewing the data and conclusions in the report relating to soy-based infant formula, SACN considered that there is cause for concern about the use of soy-based infant formula. Additionally, there is neither substantive medical need for, nor health benefit arising from, the use soy-based infant formulae ..."

So, one can see that Solae's meta-analysis of studies of various cancer studies in their submission is flawed, right from the start. Why ??. Solae admits in their application for a Qualified Health Claim for Soy and Cancer that "... the evidence in their application is not conclusive ...". Further comment on this is covered in my **3rd point** below. Therefore the conclusions Solae use to request a Qualified Health Claim from the FDA should not be accepted, and is reason enough in itself for the FDA to reject Solae's application outright. If the FDA allows Solae's application, it will be giving false hope to hundreds of millions of people around the world, and subjecting them to unnecessary and unimaginable pain and suffering and agony for the very same illness of cancer, which everyone is desperately trying to avoid.

As you can see in the 2nd abstract presented below for our consideration, this 2002 abstract on proving that soy damages the immune system is research done and payed for by the soy industry. The soy industry released the results of their own study in May **2002**. In the collection of abstracts presented in this submission of objection, and else where, there is reference and scientific research showing how important a strong immune system is for a healthy body. Actually, it is quite amazing that this **study** was even released for publication, and yet this study was funded by the United Soybean Board and the Illinois Council on Food and Agricultural Research.

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12032332 .
Proc Natl Acad Sci USA* 2002 *May 28;99(11):7616-21.

2002 "The phytoestrogen genistein induces thymic and immune changes: a human health concern ?," – *Yellayka S. and others*, Department of Veterinary Biosciences, University of Illinois, Urbana, IL 61802, USA.

– Use of soy-based infant formulas and soy/isoflavone supplements has aroused concern because of potential estrogenic effects of the soy isoflavones genistein and daidzein. Here we show that s.c. genistein injections in ovariectomized adult mice produced dose-responsive decreases in thymic weight of up to 80%. Genistein's thymic effects occurred through both estrogen receptor (ER) and non-ER-mediated mechanisms, as the genistein effects on thymus were only partially blocked by the ER antagonist ICI 182,780.

– Genistein decreased thymocyte numbers up to 86% and doubled apoptosis, indicating that the mechanism of the genistein effect on loss of thymocytes is caused in part by increased apoptosis. Genistein injection caused decreases in relative percentages of thymic CD4(+)CD8(-) and double-positive CD4(+)CD8(+) thymocytes, providing evidence that genistein may affect early thymocyte maturation and the maturation of the CD4(+)CD8(-) helper T cell lineage. Decreases in the relative percentages of CD4(+)CD8(-) thymocytes were accompanied by decreases in relative percentages of splenic CD4(+)CD8(-) cells and a systemic lymphocytopenia.

– In addition, genistein produced suppression of humoral immunity.

– Genistein injected at 8 mg/kg per day produced serum genistein levels comparable to those reported in soy-fed human infants, and this dose caused significant thymic and immune changes in mice. Critically, dietary genistein at concentrations that produced serum genistein levels substantially less than those in soy-fed infants produced marked thymic atrophy.

– These results raise the possibility that serum genistein concentrations found in soy-fed infants may be capable of producing thymic and immune abnormalities, as suggested by previous reports of immune impairments in soy-fed human infants.

More and more people are coming to realize that it is quite common for industry and corporations in general to hide and suppress findings that are quite (-)negative for their products and services. Many times, people have to use the "Freedom of Information laws" to get information that should otherwise be easily and readily available to them. A good example of this is, is in the article "Doctors Without Borders, Why You Can't Trust Doctors," or Drug Companies at ... http://www.washingtonmonthly.com/features/2004/0404.brownlee.html For examples, also, see the new 2003 movie called "The Corporation" and the book by the same name at ... http://www.thecorporation.tv/synopsis.php, and at ... http://www.thecorporation.com/, and at ... http://www.thecorporation.tv/usa/, and at ... http://www.thecorporation.tv/trailer/ .

As you read through this large and continually growing volume of well established and creditable scientific research, the evidence, showing harm to both human and animal health from consuming soy in our food supply, it is necessary to also consider a short list of internationally accepted Legal Definitions. One such Legal Term to be given serious consideration from ... **Blacks Law Dictionary, 6th Edition, 1990**, is the definition of **"The Preponderance Of Evidence"** at ... http://www.trufax.org/reports/legal.html . Think of this definition when considering the hundreds of abstracts available, the scientific evidence, on the many serious harmful side-effects from putting soy in our food supply,

> ***Preponderance of evidence*:** Evidence which is of greater weight or more convincing that the evidence which is offered in opposition to it; it may not be determined by the number of witnesses, but by the greater weight of all evidence, the opportunity for knowledge, information possessed.

The **"Hidden Harm"** caused from eating soy is considered by the soy industry as mere externalities. "An externality occurs in economics when the actions of one consumer or firm affect the well being or production of another consumer or firm with whom there is no direct business relationship." Click on this website ... http://encyclopedia.thefreedictionary.com/externality .

The concerns about the carcinogenesis of modern soy is not new. In fact , the US government, especially the Department of Agriculture scientists, also knew soy meal caused infertility. It was no secret as it was published by Chang et al in **1953.**

The scientific research in this petition of objection will show much of the scientific research on the toxic and poisonous side-effects of eating soy, and this will show that soy hasn't change in this way for over 2 thousand years, even with the modern westernized processing techniques of high heat and high pressure cooking, as the isoflavones genistein, daidzein, and **beta-Sitosterol,** will greatly reduce these natural occurring toxins, but will not eliminate. Even the soy industry admits to this and referrers to these toxins as anti-nutrients.

Here, below, is a short introductory list of 11 abstracts, a preview, just a example, of the 61 abstracts summarys in the reference section at the end of this petition, out of hundreds available from around the world. They are just some of the examples of current and past research in both vivo and vitro from hundreds available in NCBI, PubMed, that documents these many serious health hazards.

Short Introductory List

See reference section at end for 61

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15113961 .
J Nutr.* 2004 *May;134(5):1145-1151.

2004 **"beta-Sitosterol, beta-Sitosterol Glucoside, and a Mixture of beta-Sitosterol and beta-Sitosterol Glucoside Modulate the Growth of Estrogen-Responsive Breast Cancer Cells In Vitro and in Ovariectomized Athymic Mice," — *Ju YH, Clausen LM, Allred KF, and others,* *Department of Food Science and Human Nutrition and Department of Animal Sciences, University of Illinois at Urbana-Champaign, Urbana, IL 61801 USA, and Department of Physiology, University of Kentucky, Lexington, KY 40536; IMAGINutrition, and MetaResponse Science, Laguna Niguel, CA 92677, USA.***

– Further evidence from current research that beta-Sitosterol, a compound common in soy oil, and also present in soy protein, can stimulate the growth of MCF-7 breast cancer cells"

– In summary, BSS and MC stimulated MCF-7 cell growth in vitro. Although BSSG comprises only 1% of MC, BSSG made MC less estrogenic than BSS alone in vitro. However, dietary BSS and MC protected against E(2) -stimulated MCF-7 tumor growth and lowered circulating E(2) levels.

- http://www.eurekalert.org/pub_releases/2001-05/NIoE-Iucs-3005101.php .
***Cancer Research* 2002 *June, EurekAlert 31 May* 2001.**

2002 **"Increased uterine cancer seen in mice injected with genistein, a soy estrogen, as newborns," – *Newbold R. Jefferson W., Padilla E., Bullock B.C.,* Wake Forest University School of Medicine, Winston-Salem, N.C., USA,**

– Genistein is carcinogenic

– Infant mice given genistein developed cancer of the uterus later in life. "The data suggest that genistein is carcinogenic if exposure occurs during critical periods in a young animal's development."

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11250801&dopt=Abstract .

Environ Health Perspect 2001 Mar;109 Suppl 1:5-20.

2001 "Cross-species and interassay comparisons of phytoestrogen action," – *Whitten P.L., Patisaul H.B.*, *Department of Anthropology, Emory University, Atlanta, Georgia 03022*, USA.

Humans are affected at lower doses than rodents.

– This paper compiles animal and human data on the biologic effects and exposure levels of phytoestrogens in order to identify areas of research in which direct species comparisons can be made. "In vivo data show that phytoestrogens have a wide range of biologic effects at doses and plasma concentrations seen with **normal** human diets.

– Significant in vivo-responses have been observed in animal and human tests for ... bone ... breast ... ovary ... pituitary... vasculature ... prostate ... and serum lipi ds."

– The doses reported to be biologically active in humans (0.4--10 mg/kg body weight/day) are lower than the doses generally reported to be active in rodents (10--100 mg/kg body weight/day), although some studies have reported rodent responses at lower doses.

– The similarity of reported proliferative and antiproliferative doses illustrates the need for fuller examination of dose-response relationships and multiple end points in assessing phytoestrogen actions.

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10762754&dopt=Abstract .

***Eur J Cancer* 2000 Apr;36(6):796-802.**

2000 "Genistein induces apoptosis and topoisomerase II-mediated DNA breakage in colon cancer cells," – *Salti G.I., Grewal S., Mehta R.R., Das Gupta T.K., and others*, University of Illinois at Chicago, College of Medicine, Department of Surgical Oncology, Chicago, USA

– DNA breakage in colon cancer cells occurred **- within 1 hour -** of treatment with genistein.

- http://www.soyonlineservice.co.nz/Refs/Helf.htm.
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=9848512 .

***Cancer Res* 1998 *Sep 1;58(17):3833-8.*, *and* *Cancer Res* 1999 *Mar 15;59(6):1388*.**

1998 "Estrogenic effects of genistein on the growth of estrogen receptor-positive human breast cancer (MCF-7) cells in vitro and in vivo," – *Hsieh C.Y., Santell R.C., Haslam S.Z., Helferich W.G.*, Department of Food Science and Human Nutrition, Michigan State University, East Lansing 48824, USA.

– Proliferation of cultured human breast cancer cells ... Dees concluded that ' women should not consume particular foods, (eg. soy-derived products), to prevent breast cancer'.

– IN SUMMARY, genistein can act as an estrogen agonist in vivo and in vitro, resulting in the proliferation of cultured human breast cancer cells (MCF-7) and the induction of pS2 gene expression. Here we present new information that dietary genistein stimulates mammary gland growth and enhances the growth of MCF-7 cell tumors in ovariectomized athymic mice.

– Dr Craig Dees of Oak Ridge National Laboratory has also found that soy isoflavones cause breast cancer cells to grow. He reported that 'low concentrations of genistein may stimulate MC-7 cells to enter the cell cycle'. **Dees concluded that ' women "should not" consume particular foods, (eg. soy-derived products), to prevent breast cancer'.**

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9848512&dopt=Abstract .
***Am J Clin Nutr* 1998 Dec;68(6 Suppl):1431S-1435S.**

1998 "Effects of soy-protein supplementation on epithelial proliferation in the histologically normal human breast," – *McMichael-Phillips D.F. and others*, Depart. of Epithelial Biology, Paterson Institute for Cancer Research, Christie Hospital NHS Trust, Manchester, United Kindgom

– Soy foods stimulates breast proliferation ... after just 14 days

– Forty-eight women with benign or malignant breast disease were randomly assigned a normal diet either alone or with a 60 gram soy supplement containing 45 mg isoflavones, taken for 14 days. The proliferation rate of breast lobular epithelium ... significantly increased ... after just 14 days ... of soy supplementation ... when both the day of menstrual cycle & age of patient were accounted for. Thus short-term use of dietary soy containing isoflavone levels found in modern soy foods **stimulates** breast proliferation.

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10022277&dopt=Abstract .
Toxicol Lett. 1998 Dec 28;102-103:349-54.

1998 "Dietary phytoestrogens and their role in hormonally dependent disease," — *Strauss L., Santti R., Saarinen N., Streng T., Joshi S., Makela S.*, Institute of Biomedicine and Medicity Research Laboratory, University of Turku, Finland.

– Although epidemiological studies suggest that diets rich in phytoestrogens may be associated with low risk of breast and prostate cancer, **there is no direct evidence for the beneficial effects of phytoestrogens in humans.** It is plausible that phytoestrogens, as any exogenous hormonally active agent, might also cause adverse effects in the endocrine system.

– Epidemiological studies suggest that diets rich in phytoestrogens (plant estrogens), particularly soy and unrefined grain products, may be associated with low risk of breast and prostate cancer. It has also been proposed that dietary phytoestrogens could play a role in the prevention of other estrogen-related conditions, namely cardiovascular disease, menopausal symptoms and post-menopausal osteoporosis.

– However, there is no direct evidence for the beneficial effects of phytoestrogens in humans.

– All information is based on consumption of phytoestrogen-rich diets, and the causal relationship and the mechanisms of phytoestrogen action in humans still remain to be demonstrated.

– In addition, the possible adverse effects of phytoestrogens have not been evaluated.

– It is plausible that phytoestrogens, as any exogenous hormonally active agent, might also cause adverse effects in the endocrine system, i.e. act as endocrine disrupters.

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9168007&dopt=Abstract .
***Environ Health Perspect* 1997 Apr;105(Suppl 3):633-636.**

1997 "Dietary estrogens stimulate human breast cells to enter the cell cycle," – *Dees C., Foster J.S., Ahamed S., Wimalasena J.*, Health Sciences Research Division, Oak Ridge National Laboratory, Tennessee, USA

– Stimulates human breast cancer cells to enter the cell cycle

– Dietary estrogens were found to increase enzymatic activity leading to breast cancer. "Our findings are consistent with a conclusion that dietary estrogens at low concentrations do not act as antiestrogens, but act like DDT and estradiol to stimulate human breast cancer cells to enter the cell cycle.

- http://www.mercola.com/article/soy/avoid_soy.htm , **Foot Note #53.**

1992 *"Bulletin de L'Office Federal de la Santé Publique,"* No 28, July 20, 1992.

– The Swiss Health Service estimates that **100 grams of soy protein** provides the estrogenic equivalent of the **contraceptive pill.**

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=2548712&dopt=Abstract .
***Cancer Res* 1989 Sep 15;49(18):5111-7.**

1989 "Inhibitory effects of the tyrosine kinase inhibitor genistein on mammalian DNA topoisomerase II," – *Markovits J., Linassier C., Fosse P., Pierre J., and others*, Laboratorie de Pharmacologie Moleculair, URA 158 du CNRS, U 140 de I'NSERM, Institute Gustave Roussy, Villejuif, France.

– Genistein stimulates double strand DNA breaks.

– Finally, genistein treatment of DC-3F cells results in the occurrence of protein-linked **DNA strand breaks** as shown by DNA filter elution. Viscometric (lengthening) studies demonstrate that genistein isn't a DNA intercalator. Genistein is therefore an interesting compound because it induces cleavable complexes without intercalation. Taken together, our results show that genistein is an inhibitor of both protein tyrosine kinases and mammalian DNA topoisomerase II. This could be accounted for by the sharing of a common structure sequence between the two proteins at the ATP binding site.

In the reference section at the end of this submission, there are more examples of current and past abstract summaries of research in both vivo and vitro our to hundreds available world wide, that documents these and many other long known and ignored serious health hazards from putting soy in our food.

We feel that there are three errors, flaws, in Solae Corporation's application request for a Qualified Health Claim for Soy Protein and Cancer. We feel that we can demonstrate that their statements are false, distorted, slanted and misleading. Since the Solae Corporation is newly formed in around April of 2003, less than a year before they made this application, I would expect that their lack of knowledge and experience would partly, but not completely, accounts for these errors and misrepresentation(s) of the facts. We also feel that Solae knowingly used an extremely narrow selection of past research to try to bend the truth in order to try to justify and prove their flawed argument for a Qualified Health Claim for Soy and Cancer.

1 st. Point of Error By The Solae Corporation

On page 115 of the Solae's Application, in Section C: Analytical Data

I feel, as supported by the evidence here and similar facts elsewhere, there is a very inaccurate and misleading statement by Solae Corporation as to how much soy has been eaten in past centuries, and an error in the way they phrased their sentence in the application, which we feel is from either their inexperience and lack of knowledge from being a newly formed Corporation early in 2003 and / or an attempt to fool the FDA with misinformation in order to get their claim accepted.

In their inaccurate statement in their application they say that **"... Soybeans ... have been consumed as a dietary protein staple by population for centuries (Messina et al, 1994a) ...".** Without Solae including more accurate information form current and past research in order to reflect a more truthful historical statement, their sentence with its reference we feel, and as the evidence shows to knowledgeable people, is highly inaccurate and misleading as it is presently left to the understanding of both the FDA staff evaluating their application and readers from the general public at large. Without Solae writing a more complete and accurate presentation and understanding of the facts in history and the historical use of soy in Solae's application, it easily appears to an informed reader, that those who wrote this application use the words "a dietary protein staple by populations for centuries" as a smokescreen, a vague reference to how much soy they, the Solae Corporation, wants you, the FDA and the readers of their Application to believe Asians and Japanese ate in the past. What Solae wrote is a not true. Their vague reference in their sentence illustrates the great lack of historical knowledge Solae Corporation has on this topic, (or pretends to have). We feel their sentence in question here is intentionally and deliberately and purposely written to confuse and then used in order to hide from both the ill-informed general public and the FDA staff the real historical truth and real understanding of the issue(s) in order to get Solae's application in question approved by the FDA under what we feel is misinformation.

Below are fact that a company like Solae, with their limited knowledge and experience, who professes to be knowledgeable about the history should know. I feel that it is very negligent of them to have not presented these facts correctly, when the opposite of what they claim is really the true. A similar situation to that experienced from information coming from the pharmaceutical companies on their claim that Hormone Replacement Therapy, HRT, was safe and beneficial. Let me illustrate with some historical facts that should be known by the representatives of the Solae Corporation. The following facts are hopefully known by the staff in the FDA who have the authority to accept and/or reject this application. We will just mention a few of many studies on this topic.

It has been argued that high levels of soy isoflavones such as genistein and daidzein in Asian diets protect the inhabitants of Japan and China from certain degenerative diseases, especially breast and prostate cancer. Actually, consumption of soy in traditional Asian diets is low. A **1975** report lists safeties as minor sources of protein in Japan and China.**(1.)** Major sources of protein listed were meat including organ meats, poultry, fish and eggs. Average isoflavone consumption in Asian diets ranges from 10-28 mg/day, as shown in the table below. Studies indicate that isoflavone consumption at levels slightly exceeding those found in tradition diets results in thyroid suppression and endocrine disruption. The AdvantaSoyTMClearTM supplement would add 30-50 mg of isoflavones to a 100-gram serving of various common foods, levels that exceed the amounts found in traditional diets and that are in the range of levels shown to cause problems, especially for sensitive individuals. It is not only possible but likely that many individuals will consume two or more servings of foods to which the Cargill isoflavones have been added, especially as these foods will be promoted with much advertising touting their health benefits. Two or more servings of such foods would provide 60-100 mg isoflavones per day, an amount that clearly poses dangers after only a brief period of daily intake.

	Isoflavones
Japan (1996 survey),**(2.)**	10 mg/day
Japan (1998 survey),**(3.)**	25 mg/day
Japan (2000 survey),**(4.)**	28 mg/day
China (1990 survey),**(5.)**	10 mg/day
In Japanese subjects receiving adequate iodine, Soy still **causes** thyroid suppression after 3 months use,**(6.)**	38 mg/day
In American women, **causing** hormonal changes, after 1 month,**(7.)**	45 mg/day
AdvantaSoyTMClearTM.	30-50 mg/ 100 g serving

References:.

1. *Nutrition during Pregnancy and Lactation*. California Department of Health, **1975.**
2. Fukutake M, Takahashi M, Ishida K, Kawamura H, Sugimura T, Wakabayashi K. Quantification of genistein and genistin in soybeans and soybean products. *Food Chem Toxicol* **1996**;34:457-461.
3. Nagata C, Takatsuka N, Kurisu Y, Shimizu H. Decreased serum total cholesterol concentration is associated with high intake of soy products in Japanese men and women. *J Nutr* **1998** Feb;128(2):209-13.
4. Nakamura Y, Tsuji S, Tonogai Y. Determination of the levels of isoflavonoids in soybeans and soy-derived foods and estimation of isoflavonoids in the Japanese daily intake. *J AOAC Int* **2000**;83:635-650.
5. This exhaustive study of Chinese diets found that legume consumption ranged from 0 to 58 grams per day, with an average of 13 gams. Assuming that 2/3's of this is from soy beans, then consumption averages about 9 grams of soy products per day. Isoflavone content would be about 10 mg/day. Chen J, Campbell TC, Li J, Peto R. *Diet, Lifestyle and Mortality in China. A study of the characteristics of 65 counties*. Monograph, joint publication of Oxford University Press, Cornell University Press, China People's Medical Publishing House. **1990.**
6. Y Ishizuki, et al, "The effects on the thyroid gland of soybeans administered experimentally in healthy subjects," *Nippon Naibunpi Gakkai Zasshi* **1991**, 767: 622-629
7. Cassidy A, Bingham S, Setchell KD. Biological effects of a diet of soy protein rich in isoflavones on the menstrual cycle of premenopausal women. *Am J Clin Nutr* **1994**;60(3):333-340.
8. *Washington Post Health Section*, January 30, **2001.**
9. Burros M. Doubts Cloud Rosy News on Soy. *New York Times*, January 26, **2000.**

There is also the **1998** survey which found that the average daily amount of soy protein consumed in Japan was about eight grams for men and seven for women - less than two teaspoons. (**40.** Nagata, C. et al., Journal of Nutrition (1998) 128:209-213.)

Then there is also the famous Cornell China Study, conducted by Colin T. Campbell, found that legume consumption in China varied from 0 to 58 grams per day, with a mean of about twelve. (**41.** Campbell, Colin T. et al., The Cornell Project in China.) And I could go on and on, as there are other studies.

Now with this evidence, lets assume that two-thirds, (2/3's), of legume consumption is soy, then the maximum consumption is about 40 grams, or less than three tablespoons per day, with an average consumption of about nine grams, or less than two teaspoons. A survey conducted in the 1930's found that soy foods accounted for only 1.5 per cent of calories in the Chinese diet, compared with 65 per cent of calories from pork. (**42.** Chang, K.C. (ed.), Food in Chinese Culture: Anthropological and Historical Perspectives, New Haven, 1977.) Also Asians traditionally cooked with lard, not vegetable oil, which is recently being comprised of soy or mostly soy, or soy and canola.

In reality, except I times of famine, Japanese and Asians ate soy, and still do eat soy in very small amounts, as a condiment (a seasoning), not as a protein substitute, **not** as a replacement for animal foods, even fermented soy, with one exception !. Celibate monks living in monasteries and leading a vegetarian lifestyle find soy foods quite helpful because they dampen libido. Asians have been aware of the toxic, poisonous nature of soy as far back as during the **Chou Dynasty (1134-246 BC).** The Chinese did not eat unfermented soybeans as they did other legumes such as lentils, because the soybean contains large quantities of natural toxins or **"anti-nutrients"**, as the soy industry calls them. Fermentation and the western methods of processing soy only lowers the toxic levels and the toxic effects of these "anti-nutrients" in soy, but it dies not eliminate them. When precipitated soy products like tofu are consumed with meat, the mineral-blocking effects of the phytates are reduced. **(18.** Sandstrom, B. et al., **"Effect of protein level and protein source on zinc absorption in humans"**, Journal of Nutrition 119(1):48-53, January 1989; Tait, Susan et al., **"The availability of minerals in food, with particular reference to iron"**, Journal of Research in Society and Health 103(2):74-77, April 1983.) The Japanese traditionally eat a small amount of tofu or miso as part of a mineral-rich fish broth, followed by a serving of meat or fish.

Also, soy advertisers and soy manufactures, like the Solae Corporation, selectively claim lower rates of reproductive cancers for Japanese and Asians eating soy, while knowing and ignoring the fact that the Japanese and Asians also have much higher rates of cancer of the esophagus, stomach, liver, pancreas, and thyroid, particularly as soy also causes these came types of cancers in a variety of laboratory test animals. (**38.** Harras, Angela (ed.), Cancer Rates and Risks, National Institutes of Health, National Cancer Institute, 1996, 4th edition, and **39.** Searle, Charles E. (ed.), Chemical Carcinogens, ACS Monograph 173, American Chemical Society, Washington, DC, **1976.**) (and in farm animals). This also includes cancer of the pancreas (**14.** Rackis, Joseph J. et al., "The USDA trypsin inhibitor study. I. Background, objectives and procedural details", Qualification of Plant Foods in Human Nutrition, vol. 35, 1985).

2 nd. Point Of Error By The Solae Corporation

One page 13 of Solae's application is a statement for one of Solae Corporation's justifications for accepting its application on for a Health Claim for Soy Protein as it relates to Cancer, they say, ***"... the FDA has recognized soy protein products as having GRAS status at various times throughout the past three decades ...".*** We feel that this statement on the history of soy in our food supply is not true.

Unaware by the general public, the historical knowledge of the naturally carcinogenic properties of soy have a long, known, ignored and denied publically by the soy industry and the US FDA for over 40 years. We feel that the statement by the Solae Company in its application to the FDA is definitely and deliberately false, distorted, slanted and misleading because of these next points . So, Why doesn't soy protein does not have GRAS determination.

1.) Soy protein was slipped into the food chain about **1959** even though the developmental research (funded by ADM and Mead Johnson) demonstrated that it caused serious infertility problems in laboratory rats and their offspring. This is recorded in a series of papers in the **"Journal of Nutrition" by Schultze, Liener et al** in the **1950's**

2.) In **1966**, "The Committee for Food Safety" was worried about soy's carcinogenic properties.

3.) In **1972**, the Nixon administration directed a re-examination of substances believed to be GRAS (Generally Recognized As Safe), in the light of any scientific information then available. In **1974**, the FDA obtained a literature review of soy protein because, as soy protein had not been used in food until **1959** and was not even in common use in the early 1970s, it was not eligible to have its GRAS status grand-fathered under the provisions of the Food, Drug and Cosmetic Act. The scientific literature up to **1974** recognized many antinutrients in factory-made soy protein, including trypsin inhibitors, phytic acid and genistein. The FDA was more concerned with toxins formed during processing, specifically nitrites and lysinoalanine. Even at low levels of consumption - averaging one-third of a gram per day at that time - the presence of these carcinogens was considered too great a threat to public health to allow GRAS status.

History of soy ... continued.

4.) The definitive textbook **"Chemical Carcinogens"** published by the American Chemical Society in **1976** had a chapter titled **"Plant Carcinogens"** that identified soy isoflavones as known carcinogens.

5.) The only evaluation was done by The Life Sciences Committee of FASEB in its **1978 "Evaluation of Soy Products for Human Consumption"** for the Food and Drug Administration (SCOGS-101 under contract to the FDA # 223-75-2004) declined GRAS determination because of the risks of carcinogenic nitrosamines, lysinoalanines, and nitrite occurring during the modern processing, heat treatment. FASEB assumed the heat treatment was removing the natural poisons, and did not evaluate their safety at all. In a **1980** study, McGuinness E.E., it was found that long periods of heat and pressure, requiring 130 degrees Celsius, could deactivate the trypsin inhibitors, genistein, in soy, but that denatured the soy protein to the point that the protein became virtually useless. So, one was faced with either choosing less heating, resulting in more surviving poisonous trypsin inhibitors, or more heating, resulting in useless protein. Consequently, here is no standardization as to who soy protein is processes. Toxin levels can vary widely. **William Jarvis, Ph.D.,** Department of Health Promotion and Education, Loma Linda University, Loma Linda, California, USA. The FDA has imposed no requirements for manufactures to use heat treatment, or any guidelines as to how long or how high the temperature needs to be. **"The effects of long-term feeding of soya flour on the rat pancreas," — *McGuinness E.E, Morgan R.G., Levison D.A. and others* *Scandinavian Journal of Gastroenterology,* 1980*; 15(4):497-502.*** FDA officials called for safety specifications and monitoring procedures before granting of GRAS status for food. These were never performed. To this day, the use of soy protein is codified as GRAS only for the limited industrial use as a cardboard binder. This means that soy protein must be subject to premarket approval procedures each time manufacturers intend to use it as a food or add it to a food.

6.) In **1999**, an application by Archer Daniels Midland Corp for GRAS determination of GRAS (GRN 00001) for isoflavones was declined due to the failure of the applicant to reveal health risks. (Not to mention the more current scientific research documented natural occurring carcinogenic chemicals is soy called **genistein** and **daidzein** and **beta-Sitosterol** in May 2004).

You will find a fuller discussion of **GRAS** in the Home Page of www.soyonlineservice.co.nz **"Trouble for Soy Protein"**, including Dr Fitzpatrick's opposition to the grant of health claim labeling by the FDA. The material in www.soyonlineservice.co.nz **"Doses Simplified"** gives an idea of how toxic the levels of isoflavones are in the products.

In addition, Soy is in breach of, in violation of - "WHO/CODEX - Food Safety Standards," WHO/Codex General Standards for Soy Protein Products. World Health Organization, WHO/Codex Standard 175-1989 **and** WHO/Codex General Guidelines for the Utilization of Vegetable Protein Products (VPP) in Foods CAC/GL 4-1989. These standards do not allow approval of food ingredients that has been shown to have ... Subacute toxicity ... Chronic toxicity ... Reproductive toxicity ... or have ... Teralogenic effects ... mutagenic effects ... and fail to have scientific studies last at least 3 month in length. It is well documented that soy produces those health hazards banned by the WHO. When the scientific studies go into the 2nd, 3rd and 4th month and longer, this is when the serious health hazards start to show up in a variety of laboratory test animals, as is reflective of scientific research in this submission and as reported in real life experience situations. See ... http://www.soyonlineservice.co.nz/Refs/Codex.htm .

To add insult to injury, soy protein fails to meet, fulfill, and satisfy the 1958 "Delaney Amendment" to the USA's FDA Reg.'s which prohibits the use of any food additive if it is found to cause cancer in any animal species or in man, at any dose level.

Add up all this and more to "Hidden Harm" soy is doing to our health as seen in the growing list of known and ignored side-effects, and you have 100's of millions of crime scenes taking place around the world every day.

The negative health risks of soy in our food supply clearly far out weigh any claimed benefits to health.

The weed of crime bears bitter fruit. Does the soy industry and all its supporters really think they'll all get away with it ??. Do they really think I, we, wouldn't know ??.

"... Money, not truth, drives science – even at the expense of the health and lives of the nation's citizens ...", by Dr. Phyllis Mullenix, Ph.D., formerly of Harvard University, Dept. of Neuropathology and Psychiatry, See ...
Did Government Approve Citizens as Toxic Waste Sites ?, Are We Being Poisoned ?, and it is no mistake !!, at ... http://www.lef.org/fda-museum/8_water/intarticles/fluoride-01-98.html and http://www.whale.to/b/fl2.html
and http://www.fannz.org.nz/text/mullinex.html .

3 rd. Point Of Error By The Solae Corporation

Also on page 115 and 116, Section D, Model Health Claim, of the Solae Corporations Application, there are claims in two troubling request in Subsection D.1. Proposed Claims.

Solae's 1st request in Subsection D.1. Proposed Claims. "The following statement is proposed for foods that meet the qualifying criteria for the soy protein and reduced risk of certain cancers health claim:

> **A.)** "Soy protein may reduce the risk of certain cancers. Scientific evidence suggests that consumption of soy protein may reduce the risk of certain forms of cancer. However, this evidence is not conclusive."

Here, Solae freely admit that their evidence is not conclusive. Also, the research, the evidence, presented here in our submission of objection further supports Solae's statement that "... their evidence is not conclusive ...". Also, the evidence presented here **contradicts their claim of reduced cancer risk from eating soy.** In fact, the scientific research presented here, from experts in their own fields from around the world, disproves Solae's claim of cancer prevention, and proves the opposite, that is, the consumption of soy protein like soy protein isolate, SPI, does **very greatly increases the risk** of certain cancers, including breast cancer. **The negative health risks of soy in our food supply clearly out weigh any claimed or imagined benefits to health.**

Solae's 2nd request in Subsection D.1. Proposed Claims. "The following statement is proposed for foods that meet the qualifying criteria for the soy protein and reduced risk of certain cancers health claim:

> **B.)** "Soy protein may produce anti-carcinogenic effect in the body. Scientific evidence suggests that consumption of soy protein may produce anti-carcinogenic effects in the body. However, this evidence is not conclusive.

Here again, they freely admit that their evidence is not conclusive on this point as well. The research, the evidence, presented in this submission further supports their claim that "... their evidence is not conclusive ...". In fact, the scientific research presented here in our submission from around the world, again does prove the exact opposite of Solae's claim. That is, the consumption of soy protein **does not** in any way produce anti-carcinogenic effects in the body, but, the consumption of soy protein like soy protein isolate, SPI, does **very greatly increases the risk** of certain cancers, including breast cancer. **The negative health risks of soy in our food supply clearly out weigh any benefits to health.**

The evidence is Solae's application is not conclusive by their own admission. This is further evidence, extremely important evidence for the FDA to use as reason to deny, to turn down and to decline Solea Corporation's application for a Qualified Health Claim for soy and cancer. I repeat again from what I have said earlier toward the beginning of this submission ...

> In fact, in the 1998 abstract above and in the reference section below, it is stated in a meta-analysis done by ***Strauss L., Santti R., Saarinen N., Streng T., Joshi S., and Makela S.,*** at the **Institute of Biomedicine and Medicity Research Laboratory, University of Turku, Finland**, that "... there is no direct evidence for the beneficial effects of phytoestrogens in humans. ... All information is based on consumption of phytoestrogen-rich diets, and the causal relationship and the mechanisms of phytoestrogen action in humans still remain to be demonstrated ... In addition, the possible adverse effects of phytoestrogens have not been evaluated ... It is plausible that phytoestrogens, as any exogenous hormonally active agent, might also cause adverse effects in the endocrine system, i.e. act as endocrine disrupters ...".

There is still no direct evidence, nothing has changed and this is still exactly the case today as it was in 1998, and before. This is part of the reason why Solae says in their application in the 3rd point I make above that "... However, this evidence is not conclusive ...". To knowingly endanger peoples health to known and ignored health hazards, "Hidden Harm," by submitting evidence that is not conclusive, is, I suggest, a criminal act of global proportions, as is explained in quite legal detail further on in this submission.

It is deeply disturbing to Deanna, me and other dedicated and caring people who are aware of the many serious health hazards of soy in our food supply that Solae Corporations says that their request for a **Qualified Health Claim: Soy Protein and Cancer** "... is consistent with the model claims of other authorized cancer related health claims of the FDA (Dietary Fat and Cancer -& 101.73; Fiber-Containing Grain Products - & 101.76; and Fruits and Vegetable and Cancer - & 101.78 ...". It appears from Solae's request that the other claims they are referring to will also give people false hope and mislead people to an inaccurate and unsafe conclusion about soy and other soy ingredients as being safe; where as, the conclusive evidence presented by us does justify the Solae's claims about soy as "not conclusive." We feel that Solae's inconclusive claims are in effect worthless, and proof that their application should not be approved by the FDA.

But, in reality, as you read through this continually growing body of scientific research from credible medical and dietary research, **the evidence,** which includes **but is not limited to** what is presented here in this petition of objection to Solae's application for a Health Claim is conclusive in proving soy and soy protein isolate, SPI as be unsafe, and pose a clear danger to the public and should not be allowed in our food supply.

The FDA should deny Solae Corporations application and be looking for "conclusive evidence." The FDA will find "conclusive evidence" in the scientific research presented there in our submission. Evidence that shows "... soy does very greatly increases the risk of certain cancers, including breast cancer ...". Soy protein products create an **"INCREASED RISK"** of various cancers, including breast cancer.

The evidence presented here demonstrates that nothing has changed regarding the unsafe use of soy and soy protein ingredients like SPI being put in our food supply since the **Chou Dynasty (1134-246 BC).** So, this is still exactly the present situation today, as it has always been for the last couple of thousand years.

As pointed out in a very interesting article on cancer a couple of weeks ago, this month, in May **2004**, in the Vancouver Sun News paper, here in Vancouver, BC, ... with 1 in 3 women and 1 in 2 men expected to die from cancer, it is now being said that dying from cancer will be the leading cause of death in a few years ... Adding more soy to our food supply will only increase the yearly cancer deaths, along with the pain and suffering and heartache that comes from cancer. You can see that no one is safe from the very many harmful and sometimes deadly side-effects of eating soy. One can easily conclude that if soy is recommend to any one, many people could be faced with a reoccurrence of cancer from eating soy. Recommend soy to anyone and you are participating in unimaginable pain and suffering to millions, as well as in mass murder. Like **Dr. Samuel Epstein, MD** of the "Cancer Prevention Coalition" says in the **2003** movie **"The Corporation"** at ... http://www.thecorporation.tv/synopsis.php , and at ... http://www.thecorporation.com/ , ... dying from chemical poisoning is really no different than if a gun was put to your head and someone else pulled the trigger. Chemical poisoning is just a lot slower that's all ... Murder is still Murder.

If the Solae Corporation's application is approved, how will the general public at large, present and past cancer patients, and other people suffering from serious illness listed in the list of known and ignored side-effects caused from and by eating soy, under **"Hidden Harm"**, be able to avoid these harmful and sometime deadly side-effects when eating soy ingredients in our food like SPI ??. Safety starts at the top, with the FDA, and the trust the general public puts in the FDA to protect them from harmful, toxic, poisonous, and sometimes deadly ingredients in our food supply. Safety is no accident, and those in the FDA with the decision making process to deny Solae's application must exercise their power and deny Solae's application. Also the FDA has the power to stop further poisoning of our food supply with soy ingredients like SPI form other soy manufactures as well. With our objection, and the evidence presented here, we also request that the FDA rescind and repeal the "Self Determination" ability for corporations to give soy Self Determined GRAS status.

Pregnant women and their unborn child are at risk from soy ingredients in our food supply. The toxic ingredient in soy genistein cross the placenta and blood-brain barrier, "teratogenic," causing birth defects. The placenta does not represent a barrier to these poisons. See abstracts in reference section below for documentation of this.

"Toxic Load" means that ... the risk is a function of dose length, dose strength, and of the physical condition of the consumer.
References: "The Dose Makes the Poison: A Plain-Language Guide to Toxicology," 2nd Edition, **1996**, by M. Alice Ottoboni., and **"Principles of Toxicology,"** by Casarett and Doull.

Remember, when the Titanic sank early Monday morning of April 15th, 1912. **It was women and children and the elderly who were put into the life boats first.** Well, it is kind of in the same way with soy being put into our food supply without our consent. It is also women, children, the pregnant women and her fetus and the elderly who are harmed first, injured first, and injured the worst from soy being put in our food supply. Kind of psychopathic don't you think. See reference to the **2003** movie **"The Corporation,"** here page 22.

Deonaa and Gerald Hernesmaa now urgently urge you, the FDA, to now follow the same course of action taken in 1978 and in 1999, and do "The Right Thing", the "Humanitarian" thing to do, the "Ethical" thing to do, and that is to deny, to turn down and to decline Solae Corporation's application for a Qualified Health Claim for soy and cancer, or any similar application in the future from them or any other corporation or business, based on but not limited to the documented evidence in this and other submissions of objection you have received, and the use of the "*The Precautionary Principle*".

The use of the Precautionary Principle at ... http://www.biotech-info.net/rachels_586.html says that people have a duty to take anticipatory action to prevent harm. If you have a reasonable suspicion that something bad might be going to happen, you have an obligation to try to stop it. Why ??. Because FDA knows of the "Hidden Harm" people are experiencing from soy ingredients in our food supply. The Precautionary Principle is not really New. It is captured in common-sense aphorisms down throughout history, such as "An ounce of prevention is worth a pound of cure" ... "Better safe than sorry" ... "Look before you leap" ... "Error on the side of caution" ... etc., etc., etc.

The Principle of Precautionary Action has 4 parts:

1.) People have a duty to take anticipatory action to prevent harm. (As one participant at the Wingspread meeting summarized the essence of the precautionary principle, "If you have a reasonable suspicion that something bad might be going to happen, you have an obligation to try to stop it.").
2.) The burden of proof of harmlessness of a new technology, process, activity, or chemical lies with the proponents, not with the general public.
3.) Before using a new technology, process, or chemical, or starting a new activity, people have an obligation to examine "a full range of alternatives" **including ... the alternative of doing nothing,** (in order to protect the health and well-being of others.).
4.) Decisions applying the precautionary principle must be "open, informed, and democratic" and "must include affected parties."

More and more people are realizing that the original petition submitted by Protein Technologies International, PTI, requested that the health claim be made for the soy isoflavones, the plant estrogens found abundantly in soybeans, provided only weak and conflicting proofs that isoflavones lower cholesterol and besieged by strong evidence of toxicity and hormone disruption, the FDA should have thrown out the PTA petition. It had a duty to do so.

But instead, in 1998 the FDA took the unprecedented step of rewriting PTI's petition and substituting a claim for soy protein. This step violated the industry's own regulations. Then the FDA speeded the decision-making process by reducing the time in which members of the public could protest to only 30 days. In doing so, they disregarded the testimony of ... top scientists at the FDA's own National Center of Toxicological Research ... British government researchers (1998) ... and other qualified experts ... all of which were providing strong evidence of danger from allergens, protease, inhibitors, and other soy components as well as the plant hormones.

It's all the more shocking because the FDA never had good evidence of soy's cholesterol lowering effect to begin with !. The FDA relied almost entirely on just one study — a 1995 meta analysis of 29 studies by James W. Anderson that was sponsored by Protein Technologies International. Then on Oct. 25, 1999, US FDA allowed a health claim for soy. By 1995 there was tons of proof that soy had many health hazards including causing cancer cells to grow. But in 1999, the FDA granted a Health Claim for soy anyway.

More and more people are coming to understand that the USA's FDA has a unique procedure ... It was designed by industry, which lobbied for its substitution in place of normal GRAS requirements. It is called "self-determination," meaning that a manufacturer provides its own evaluation of the "safety" of its product. Then the FDA advertises in the Federal Register, which is not really a widely read document. If no citizen objects, the FDA rubber stamps its approval and a multi-million-dollar win is showered on the applicant. This then becomes the benchmark for every other promotion of similar products. The US Center for Food Safety and Applied Nutrition (CF-SAN) does not investigate for itself, and there rarely is an objection because the ultimate consumer does not have a clue about the procedure.

"This self-determination procedure," referred to above, is making the soy industry and those supporting it and making money from soy, very liable to legal action (Class Action Law Suit) from problems caused by soy being put in our food supply, from soy poisoning our food supply worldwide. As proof of this, I recommend the following. Part-3 of ... "The News Research On Why You Should Avoid Soy," "Soy The Next Asbestos," at ... http://www.mercola.com/article/soy/avoid_soy.htm by Sally Sallon and Mary G. Enig, Ph.D., partly quoted below.

Soy - The Next Asbestos ??.

- http://www.mercola.com/article/soy/avoid_soy.htm -

Because the industry is extremely exposed ... contingency lawyers will soon discover that the number of "potential plaintiffs" can be counted in the millions and the pockets are very, very deep. Juries will hear something like the following: "The industry has known for years that soy contains many toxins."

"At first they told the public that 1.) the toxins were removed by processing. When it became apparent that processing could not get rid of them, 2.) they claimed that these substances were beneficial. Your government granted a health claim to a substance that is poisonous, and the industry lied to the public to sell more soy."

The "industry" includes ... merchants ... manufacturers ... scientists ... publicists ... bureaucrats ... former bond financiers ... food writers ... vitamin companies ... and retail stores. Farmers will probably escape because they were duped like the rest of us. But they need to find something else to grow before the **Soy bubble bursts** and the market collapses: grass-fed livestock ... designer vegetables ... or hemp to make paper for thousands and thousands of legal briefs (that are sure to come and will soon follow).

The negative health risks of soy in our food supply clearly out weigh any imagined or claimed health benefits

"... Imagine having drugs, (genistein, diadzein), (beta-Sitosterol), added to our food which have been scientifically proven, for nearly 25 years, to be carcinogenic and to also cause DNA and chromosome damage in both humans & in animals. **Also,** imagine these drugs being prescribed and administered through our food supply **without** the individual's **prior** knowledge or understanding of these dangers, or **prior** consent to be exposed to these dangers. **Now**, imagine the entire population in many countries around the world, including ours, consuming these foods ... with no medical way of tracking dosage, individual reactions, or harmful side-effects, and, without any concern for some people's **increased vulnerability** from being exposed to these drugs, such as cancer patients. **Does all this sound a little crazy ??**. Well, I'll tell yeah, this is exactly what is happening to us when **Soy** is added to our food supply. **Soy** contains the **"naturally toxic"** ingredients **genistein** and **daidzein** which have been scientifically documented, proven, to be carcinogenic, **cause** DNA and chromosome damage, and to **cause** cancer cells to grow. **Soy** can also **cause** non-cancerous tumors to turn cancerous ...". **Soy** does all this and more, as these are only some of the many **health hazards** associated with eating soy.

"... Money, not truth, drives science – even at the expense of the health and lives of the nation's citizens ...", by Dr. Phyllis Mullenix, Ph.D., formerly of Harvard University, Dept. of Neuropathology and Psychiatry, See ...
Did Government Approve Citizens as Toxic Waste Sites ?, Are We Being Poisoned ?, and it is no mistake !!, at ... http://www.lef.org/fda-museum/8_water/intarticles/fluoride-01-98.html and http://www.whale.to/b/fl2.html
and http://www.fannz.org.nz/text/mullinex.html .

Deanna and Gerald Hernesmaa are shocked that a publicly held corporation would seek health **benefit** claims - labeling, without revealing at the same time to the FDA and to the general public at large, both past and present scientific research that very clearly documented risks of cancer causation and cancer cell growth acceleration, and other serious health problems, by the use of these same products, namely soy and soy ingredients like soy protein isolate, SPI, being put in our food. People have the right to know of the health hazards they are being exposed to with our their consent. Without informing people of this danger, the soy industry, their supporters, and even the all powerful FDA are viewed as being corrupt by people who know the truth, by people who have been injured by soy before they found out the truth about soy. We feel the "evidence" in this submission shows that the soy industry and its supporters are willing participants in putting poison in our food supply, and the unnecessary sickness and death that come from it. We also feel that the people in authority in the FDA who have the influence and power of authority to put a stop to this, should put a stop to this, instead of continuing to allow soy to be put in our food supply. **Genistein** in soy is a dietary topoisomerase II-poison, it accumulates in the body over time building up a toxic load and causes DNA double strand breaks leading to chromosomal aberrations and leukemia's. **Genistein** also destroys myelin sheath protecting nerves, leading to "Alzheimer's and Parkinson's disease", and learning disabilities as in ADD/ADHD.

The Solae Corporation is in a conflict of interest in making their application for a Qualified Health Claim for Soy Protein and Cancer. Like any "Corporation," would. The Solae Corporation's legal requirement under the law, as a Corporation, is to move product, find new ways to use soy products, sell as much product to maximize company profits for its shareholder's, even at the expense of the public good, and the good of the environmental. See the 2003 movie The Corporation at ... http://www.thecorporation.tv/synopsis.php. and at ... http://www.thecorporation.com/ , and below in this essay. What any business needs is customer loyalty which also helps a very great deal in maximizing company profits. But what is pointed out in Helke Ferrie's book "Hippocrates in the land of OZ, A Survival Guide for our Golden Age of Medicine," is that you can't have customer loyalty if the customer can't ignore the negative side-effects of the drugs they are taking if there is also natural, low or no side-effect choices available to them. So, one way to get the customer to ignore the negative side-effects as long as possible, not tell any one as much as possible about the negative side-effects. That way when they eventually have them, they will only turn to the pharmaceutical companies to by drugs to temporarily counter-act the negative side-effects. The FDA should and needs to realize that this is exactly what the soy industry is doing. Not telling people about these negative side effects, many people never realize in their life time that it was soy and soy ingredients like Soy Protein Isolate, SPI, that played a major roll in causing their illness and/ or death. To avoid this terrible problem, there are laws that pharmaceutical companies must follow to inform people of the side-effects of their drugs, when they advertise the benefits of a drug. But, there is no such law requiring the soy industry, manufactures and sellers of soy products and soy ingredients to inform the consumer about the many negative and sometimes deadly side-effects of soy and soy ingredients in our foods supply. This is a violation of the customers lawful "Right to Know."

Legal Definitions

http://www.trufax.org/reports/legal.html

We feel that the soy industry and those who have the power to stop soy being put into our food supply are guilt of inflecting untold, incalculable, "unimaginable" and needless pain, suffering, agony and torture onto tens of millions of innocent people around the world, by their actions, which include but are not limited to the following legal definitions taken from **Blacks Law Dictionary, 6th Edition, 1990**

> ***Negligence*:** Omission which a reasonable person, guided by ordinary considerations which ordinarily regulate human affairs, would do, or the doing of something which a reasonable and prudent person would not do; conduct which falls below the standard established by law for the protection of others from unreasonable risk of harm.
>
> ***Willful Misconduct*:** Conduct committed with an intentional or reckless disregard for the safety of others, or with an intentional disregard of a duty necessary to the safety of another's property.

Because of this, one might conclude that there is ...

> ***Criminal Gross Negligence*:** Negligence that is accompanied by acts of commission, or omission of a wanton or willful nature, showing a reckless or indifferent disregard of the rights of others, under circumstances reasonably calculated to produce injury, or which make it probable that injury will be occasioned, and the offender knows or is charged with knowledge of the probable results of his acts.

Legal Definitions

Continued

Criminal Behavior: Conduct which causes any social harm which is defined and made punishable by law, presuming the law exists which covers the action

Quasi Crimes: All offenses not crimes or misdemeanors, but that are in the nature of crimes; a class of offenses against the public which have not been declared crimes, but wrongs against the general or local public which should be punished by penalties.

Criminal Homicide: Criminal homicide constitutes murder when it is committed purposely or knowingly, or committed recklessly under circumstances manifesting extreme indifference to the value of human life.

Which have Deprived people of their right to ...

Informed Consent: A person's agreement to allow something to happen, based on full disclosure of the facts needed to make the decision intelligently; i.e., knowledge of risks involved, alternatives, etc.; the general principle of law embodying the duty to disclose to another whatever risks might be incurred from a proposed course of treatment, so that a person, exercising ordinary care for his own welfare, and faced with a choice of undergoing the proposed treatment, or alternative treatment, or none at all, may intelligently exercise his judgment by reasonably balancing the probable or possible risks against the probable or possible benefits.

Resulting from ...

Deceit: A fraudulent and deceptive misrepresentation, artifice, or device, used by one or more persons to deceive and trick another, who is ignorant of the true facts.

Misrepresentation: Any manifestation by words or other conduct not in accordance with the facts; an untrue statement of fact; an incorrect or false representation which, if accepted, leads the mind to an apprehension of a condition other and different from that which exists.

Because of ...

Fraud: An intentional perversion of the truth for the purpose of inducing another in reliance upon it to part with some valuable thing or to surrender a legal right; a false representation of a matter of fact, whether by words ot conduct, by false or misleading allegations, or by concealment of that which should have been disclosed, which deceives and is intended to deceive another so that he shall act upon it to his legal inquiry; anything calculated to deceive, whether by a single act or combination, or by suppression of truth, or suggestion of what is false, whether it be by direct falsehood or innuendo, by speech or silence, word of mouth, or look or gesture; fraud comprises all acts, omissions, and concealments involving a branch of legal or equitable duty and resulting in damage to another.

Fraudulent Concealment: The hiding or suppression of a material fact or circumstance which the party is legally or morally bound to disclose, in order to prevent inquiry, escape investigation, or to mislead or hinder the acquisition of information disclosing a right of action.

Fraudulent Intent: Such intent exists where one, either with a view of benefitting oneself or misleading another into a course of action, makes a representation which one knows to be false or which one does not believe to be true.

The weed of crime bears bitter fruit. Does the soy industry and all its supporters really think they'll all get away with it ??. Do they really think I, we, wouldn't know ??.

In conclusion, the totality of the publicly available scientific evidence, ***Preponderance of evidence*:** on the harmful and sometimes deadly side-effects of putting soy ingredients in our food supply like Soy Protein Isolate, SPI, supports the substance/ disease relationship that consumption of soy protein-containing foods is associated with an INCREASED risk of various cancers, including but not limited to breast cancer in women and men and young adults, and a variety of cancers in a variety of laboratory test animals and farm animals. Even research proving serious health hazards from the American and Canadian Cancer Institutes and Societies.

As pointed out earlier as a significant part of our evidence, Solae Corporation says in their application that their evidence is not conclusive by their own admission. But they want to persuade, lie, to people again that soy is safe to eat, when human and animal studies support epidemiological findings that consumption of soy-protein containing foods is related to an INCREASE risk of cancers, including but not limited to breast cancer, prostate cancer, colon cancer.

This is further evidence, extremely important evidence, as solid reasons to deny, to turn down and to decline Solae Corporation's application for a Qualified Health Claim for soy and cancer. To endanger peoples health to known health hazards by submitting evidence in Solae's application that is not conclusive, is, I suggest, a criminal act of global proportions, as is explained in quite legal detail further on in this submission.

In legal terms around the world, a Corporation is a person in law. But what kind of a person is it ??. In the 2003 movie **"The Corporation,"** it is pointed out quite clearly that in law a corporation must make as much money for its share holders as possible, even if it goes against the public good, the public's well-being of health and safety. In the movie they quote ways to evaluate the nature of a person, or a Corporation according to the **WHO, World Health Organization, WHO, Personality Diagnostic Checklist, ICD - 10 , Manual of Mental Disorders DSM - IV.** In that Manual it says that when a person satisfies the following criteria, displays conduct of the following distinguishable characteristics, than that person and or organization is diagnosed as having a Psychopath Personality Disorder.

"The Corporation"

http://www.thecorporation.tv/splash
Produced right here in Vancouver, B.C., Canada
Synopsis of the film at ... http://www.thecorporation.tv/synopsis.php.
A documentary film delves into the "nature" of an Institution
Based on the book by Joel Bakan
"The Corporation - The Pathological Pursuit of Profit & Power"
http://gallery.bcentral.com/Gallery/ProductListing.aspx?GID=5059307&Dept=358159&searchString=&page=1 .

Personality Diagnostic Checklist

WHO, World Health Organization ICD - 10
Manual of Mental Disorders DSM - IV

In law, the Corporation is a "person" ... But, what kind of person is it ??.

Subject: The Corporation, (and its distinguishable characteristics)

- ? **Callous unconcern for the feelings of others.**
- ? **Deceitfulness: repeated lying and conning others for profit**
- ? **Incapacity to maintain enduring relationships.**
- ? **Incapacity to experience guilt.**
- ? **Reckless disregard for the safety of others.**
- ? **Failure to conform to social norms with respect to lawful behaviors.**

The Diagnosis: Psychopath Personality Disorder

So I ask you to consider the following. How will the general public at large, present and past cancer patients and other people suffering from those illness listed in the list **"Hidden Harm"** of known and ignored side-effects caused from and by eating soy, be able to protect themselves, and the ones they love from these harmful and sometime deadly side-effects from soy ingredients in our food like SPI, if the Solae Corporations application for a Qualified Health Claim is approved ??. Even those in the FDA want to protect the ones they love as well. **Safety starts at the top, with the FDA,** and the trust the general public puts in the FDA to protect them from harmful, toxic, poisonous, and sometimes deadly ingredients in our food supply. **Safety is no accident,** and those in the FDA with the authority and the decision making process to deny this application from Solae, also have the power to stop poisoning our food supply with soy ingredients like SPI, from the Solae Corporation or any soy business or anyone else.

Deonaa and Gerald Hernesmaa now urgently urge you, the FDA, to now follow the same course of action taken by the FDA in 1979 and in 1999, and do "The Right Thing", the "Humanitarian" thing, the "Ethical" thing, and that is to deny, turn down and decline Solea Corporation's application for a Qualified Health Claim for Soy and Cancer, or any similar application in the future from them or anyone else, based on but not limited to the documented evidence in this and other submissions of objection you have received, and the use of the ***"The Precautionary Principle".***

"Propaganda" ... "is the systemic propagation of a given doctrine or of allegations reflecting its views and interests; material disseminated by the advocates of a doctrine." The promotion of **soy** as a miracle food has been both systematic and reflective of the doctrine of the food industry — that imitation foods are good for us and traditional foods are unhealthy. The soy campaign is, in fact, a case study in the use of propaganda to promote commercial interests," (above Health, Safety and the Well-being of the general population and customer base of the soy industry), http://www.mercola.com/2001/apr/7/soy.htm .

"Strong and Wrong" - verus - "Weak and Right" ... The soy industry ... one of the world's most wealthy, influential and powerful business organization ... funds millions of dollars of soy research and advertising each year in order to increase sales; so, what chance is there for discovers of soy toxins to get funding to continue their work of **exposing the truth** about the many serious and deadly health hazards of eating soy ??

These 61 abstracts are only some, out of hundreds available in NCBI PubMed, from the continually growing body of scientific research on the many "health hazards" of eating soy, of putting soy in our food supply. With the scientific evidence that follow, think about all of these known and ignored "side-effects" listed here. Now, you can begin to start counting the number of people, worldwide, likely to be seriously hurt and/or dying from eating soy simply because of what these people were told, were tricked into believing, were lied to, most of the time deliberately, with misinformation, which "persuaded" them to believe, persuaded to trust, to have false hope, by the soy industry and their supporters, world wide, which goes something like this ... "Trust us, using soy is going to help (you)them, even help save (your)their life" ... when in reality, soy is slowly and "violently killing them".

The weed of crime bears bitter fruit. Does the soy industry and all its supporters really think they'll all get away with it ??. Do they really think I, we, wouldn't know ??.

Yours Sincerely,
Deanna-(Deonaa) and Gerald Hernesmaa

P. S. This paragraph is added June 6, 2004 to the email copy. My wife Deanna-(Deonaa) Hernesmaa died from breast, bone, liver cancer while and **from** eating soy ingredients like Soy Protein Isolate, SPI, in her food. She died on Dec. 15, 2002. She also had 3 reoccurrences of cancer while and **from** eating these soy ingredients. Because we **"never gave our consent"** to have soy ingredients in her food, based on Dr. Samuel Epstein comments page 17 of this petition of objection to the FDA, and **"the evidence"**-(which includes but is not limited to what is presented here), "...the estrogens in soy ingredients and the soy industry who puts them in our food, poisoned then murdered my wife, in much in the same way the estrogens in Hormone Replacement Therapy is killing women-(with cancers)...". **Einstein said,** "...the world is a dangerous place to live in, not because of the people who are evil, but because of the people who don't do anything about it...".

Next:

61 - Scientific Research Abstract Studies, out of hundreds available from around the world, (done in vivo and vitro), documenting the presently known, ignored and yet still denied, (by the soy industry and its supporters), the many harmful and sometimes deadly side-

61 - Research Abstract References

Hidden Harm

Just some out of hundreds of Scientific Research available from around the world documenting the harmful side-effects to human and animal health from putting soy in our food supply.

Known, Ignored, Still Denied

?

New, not in 132 page soy research paper

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=14578162 .

Carcinogenesis. 2004 Feb;25(2):211-8. Epub 2003 Oct 24.

2004 Dietary genistein results in larger MNU-induced, estrogen-dependent mammary tumors following ovariectomy of Sprague-Dawley rats, — *Allred C.D., Allred K.F., Ju Y.H., Clausen L.M., Doerge D.R., and others*, *Department of Food Science and Human Nutrition, University of Illinois, Urbana, IL 61801, USA.*

— Due to the estrogenic properties of soy-derived isoflavones, many postmenopausal women are using these compounds as a natural alternative to hormone replacement therapy (HRT).

— **Genistein at 750 p.p.m. increased the weight of estrogen-dependent adenocarcinomas** in ovariectomized rats compared with the negative-control animals.

— Genistein treatment also resulted in a higher percentage of proliferative cells in tumors and increased uterine weights when compared with negative-control animals.

— **Collectively,** these effects are probably due to the estrogenic activity of genistein.

— **Plasma genistein concentrations in animals fed the isoflavone-containing diet** were at physiological levels relevant to human exposure. Estradiol concentrations in ovariectomized animals not receiving an estradiol supplement were similar to those observed in postmenopausal women.

— The data suggest that in an endogenous estrogen environment similar to that of a postmenopausal woman, dietary genistein can **stimulate** the growth of a mammary **carcinogen MNU-induced estrogen-dependent mammary tumors**.

Page 130, (from the 132 page soy research paper)

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15113961 .

J Nutr. 2004 May;134(5):1145-1151.

2004 "beta-Sitosterol, beta-Sitosterol Glucoside, and a Mixture of beta-Sitosterol and beta-Sitosterol Glucoside Modulate the Growth of Estrogen-Responsive Breast Cancer Cells In Vitro and in Ovariectomized Athymic Mice," — *Ju YH, Clausen LM, and others*, *Department of Food Science and Human Nutrition and Depart. of Animal Sciences, University of Illinois at Urbana-Champaign, Urbana, IL 61801 USA, and Department of Physiology, University of Kentucky, Lexington, KY 40536; IMAGINutrition, and MetaResponse Science, Laguna Niguel, CA 92677, USA.*

— Further evidence from current research that beta-Sitosterol, a compound common in soy oil, and also present in soy protein, can stimulate the growth of MCF-7 breast cancer cells"

— In summary, BSS and MC stimulated MCF-7 cell growth in vitro. Although BSSG comprises only 1% of MC, BSSG made MC less estrogenic than BSS alone in vitro. However, dietary BSS and MC protected against E(2) - stimulated MCF-7 tumor growth and lowered circulating E(2) levels.

References
Scientific Abstract from around the world
Continued

Page 71, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=14709783 .
Exp Biol Med (Maywood).* 2004 *Jan; 229(1):108-17.

2004 "Effects of genistein or soy milk during late gestation and lactation on adult uterine organization in the rat," – *Hughes CL, Liu G, Beall S, Foster WG, Davis V.*, *Department of Medical and Scientific Services, Quintiles, Inc., Research Triangle Park, North Carolina 27709, USA.*

Malnutrition ... from ... False nutritional beliefs.

— These experiments demonstrate that developmental exposure to dietary isoflavones, at levels comparable to the ranges of human exposure, modify expression of the estrogen-regulated PR in the uterus of sexually mature rats weeks after exposure ended.

— In utero and lactational exposure to estrogenic agents has been shown to influence morphological and functional development of reproductive tissues. Thus, consumption of dietary phytoestrogens, such as isoflavones, during pregnancy and lactation could influence important periods of development, when the fetus and neonate are more sensitive to estrogen exposure.

— In this study, reproductive outcomes after developmental exposure to isoflavones were examined in Long-Evans rats maternally exposed to isoflavones via a commercial soy beverage or as the isolated isoflavone, genistein. … … .

— Since the PR is essential for regulating key female reproductive processes, such as uterine proliferation, implantation, and maintenance of pregnancy, its increased expression suggests that soy phytoestrogen exposure during reproductive development may have long-term reproductive health consequences.

Page 57
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12738504&dopt=Abstract .
Fertil Steril* 2003 *May;79(5):1112-1117.,

2003 "Effect of soy-derived isoflavones on hot flushes, endometrial thickness, and the pulsatility index of the uterine and cerebral arteries," – *Penotti M., Fabio E., and others*, *Second Department of Obstetrics and Gynecology of the University of Milan, Milan, Italy.*

— Daily administration of 72 mg of soy-derived isoflavones is no more effective than placebo in reducing hot flushes in postmenopausal women.

Page 57
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12704663&dopt=Abstract .
Int J Cancer* 2003 *Jun 20;105(3):312-20.,

2003 "Cell-transforming activity and mutagenicity of 5 phytoestrogens in cultured mammalian cells," – *Tsutsui T, Yaqi E, and others*, *Depart. of Pharmacology, Nippon Dental University, School of Dentistry Tokyo, Japan*

— genistein ... daidzein ... suggesting the possible involvement of mutagenicity in the initiation of "phytoestrogen-induced carcinogenesis ."

References
Scientific Abstract from around the world
Continued

* * *

Frying The Brain

With Soy

(These next 2 abstracts and many others)

Page 54, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12566171&dopt=Abstract .
***Neurosci Lett* 2003 *Feb 27;338(2):135-38*.,**

2003 "Soya phytoestrogens change cortical and hippocampal expression of BDNF mRNA in male rats," – *File SE, Hartley DE, Alom N.*, Psychopharmacology Research Unit and Biochemical Neuropharmacology Group, Centre for Neuroscience Research, King's College London, Hodgkin Building, Guy's Campus, SE1 1UL, London,

— significant reductions were found in brain-derived neurotrophic factor (BDNF) mRNA expression in the CA3 and CA4 region of the hippocampus and in the cerebral cortex in the rats fed the diet containing phytoestrogens, compared with those on the soya-free diet.

Page 54
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9387865&dopt=Abstract .
***Brain Res Mol Brain Res.*, 1997 *Oct3;49(1-2):71-81*.,**

1997 "Brain-derived neurotrophic factor is reduced in Alzheimer's disease," – *Connor B, Young D, Yan Q, and others.*, Department of Pharmacology, Faculty of Medicine and Health Science, University of Auckland, New Zealand.

— BDNF mRNA is reduced in the human Alzheimer's disease hippocampus and temporal cortex, and suggest that a loss of BDNF may contribute to the progressive atrophy of neurons in Alzheimer's disease.

* * *

Page 48
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12270219&dopt=Abstract .
***J Chromatogr B Analyt Technol Biomed Life Sci* 2002 Sep 25;777(1-2):269-79.**

2002 "Inactivation of thyroid peroxidase by soy isoflavones, in vitro & in vivo,"– *Doerge D.R. & Chang H.C.*, Division of Biochemical Toxicology, National Center for Toxicological Research, 3900 NCTR Road, Jefferson, AR 72079, USA.

— implications for reproductive toxicity and carcinogenesis - warrants further investigation
— further study of auto-immune thyroiditis in children consuming Soy formula is warranted
— the results were additive ... joint action of estrogenic chemicals ... lead to significant underestimations of risk.

References
Scientific Abstract from around the world
Continued

Page 48, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11888703&dopt=Abstract .
***Toxicol Lett* 2002 Mar 28;129(3):199-205.**

2002 "Detection of phytoestrogens in samples of second trimester human amniotic fluid," – *Foster W.G. and others*, Center for Women's Health, Cedars-Sinai Medical Center, Los Angeles, California, USA

— The study describes a method for measuring phytoestrogens daidzein and genistein in amniotic fluid. Such tests are needed, the authors assert, because "There is widespread concern that fetal exposure to hormonally active chemicals may adversely affect development of the reproductive tract."

Page 48
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11993873&dopt=Abstract .
***Environ Sci Technol* 2002 Apr;36(8):1751-6.**

2002 ""Something from "nothing" - - eight weak estrogenic chemicals combined at concentrations below NOECs produce significant mixture effects," – *Silva E. and others*, Centre for Toxicology, Department of Pharmacology, The School of Pharmacy, University of London.

— Hazard assessments that ignore the possibility of joint action of estrogenic chemicals will almost certainly lead to significant underestimations of risk."
The results were additive ... joint action of estrogenic chemicals lead to significant underestimations of risk.

Page 49
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12060828&dopt=Abstract .
***Environ Health Perspect* 2002 Jun;110 suppl 3:349-53.**

2002 "Goitrogenic and estrogenic activity of soy isoflavones," – *Doerge D.R. and D.M. Sheehan*, Division of Biochemical Toxicology, National Center for Toxicological Research, Jefferson, Arkansas, USA.

— Although safety testing of natural products, including soy products, is not required, the possibility that widely consumed soy products may cause harm in the human population via either or both estrogenic and goitrogenic activities is of concern."

Page 51
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12093826&dopt=Abstract .
***Hum Reprod* 2002 Jul;17(7):1692-703.**

2002 "Infant feeding with soy formula milk: effects on the testis and on blood testosterone levels in marmoset monkeys during the period of neonatal testicular activity," – *Sharp R.M. and others*, MRC Human Reproductive Sciences Unit, Centre for Reproductive Biology, 37 Chalmers Street, Edinburgh EH3 9ET, UK.

— Infant male marmoset monkeys were fed either soy-based or milk-based formula. The neonatal testosterone rise was suppressed in the soy-fed monkeys. Levels of isoflavone in the monkey diets were 40-87% of that reported in 4-month human infants fed a 100% soy-based formula diet.
— "It is therefore considered likely that similar, or larger, effects to those shown here in marmosets may occur in human male infants fed with SFM [soy formula milk]."

References
Scientific Abstract from around the world
Continued

Page 69, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12297547&dopt=Abstract .
***Bio Reprod* 2002 *Oct;67(4): 1285-96*.**

2002 "Neonatal exposure to genistein induces estrogen receptor (ER)alpha expression and multioocyte follicles in the maturing mouse ovary: evidence for ERbeta-mediated and nonestrogenic actions," – *Jefferson W.N., Couse J.F., Padilla-Banks E., Korach K.S., Newbold R.R.*, Developmental Endocrinology Section, Laboratory of Molecular Toxicology, Environmental Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina 27709, USA.

— These data taken together demonstrate alterations in the ovary following neonatal exposure to genistein. Given that human infants are exposed to high levels of genistein in soy-based foods, this study indicates that the effects of such exposure on the developing reproductive tract warrant further investigation.

Page 52
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11836067&dopt=Abstract .
***Neurotoxicol Teratol* 2002 Jan-Feb;24(1):5-16.**

2002 "Neurobehavioral effects of dietary soy phytoestrogens," – *Lephard E.D. and others*, Neuroscience Center, 633 WIDB, Brigham Young University, Provo, UT 86402, USA.

— short interval of consumption can significantly alter sexually dimorphic brain regions, anxiety, learning and memory ... Alzheimer's disease, especially in women.

Page 51
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12032332 .
***Proc Natl Acad Sci USA* 2002 *May 28;99(11):7616-21*.**

2002 "The phytoestrogen genistein induces thymic and immune changes: a human health concern ?," – *Yellayka S. and others*, Department of Veterinary Biosciences, University of Illinois, Urbana, IL 61802, USA.

— Use of soy-based infant formulas and soy/isoflavone supplements has aroused concern because of potential estrogenic effects of the soy isoflavones genistein and daidzein. Here we show that s.c. genistein injections in ovariectomized adult mice produced dose-responsive decreases in thymic weight of up to 80%. Genistein's thymic effects occurred through both estrogen receptor (ER) and non-ER-mediated mechanisms, as the genistein effects on thymus were only partially blocked by the ER antagonist ICI 182,780. Genistein decreased thymocyte numbers up to 86% and doubled apoptosis, indicating that the mechanism of the genistein effect on loss of thymocytes is caused in part by increased apoptosis. Genistein injection caused decreases in relative percentages of thymic CD4(+)CD8(-) and double-positive CD4(+)CD8(+) thymocytes, providing evidence that genistein may affect early thymocyte maturation and the maturation of the CD4(+)CD8(-) helper T cell lineage. Decreases in the relative percentages of CD4(+)CD8(-) thymocytes were accompanied by decreases in relative percentages of splenic CD4(+)CD8(-) cells and a systemic lymphocytopenia.

— In addition, genistein produced suppression of humoral immunity. Genistein injected at 8 mg/kg per day produced serum genistein levels comparable to those reported in soy-fed human infants, and this dose caused significant thymic and immune changes in mice.

— Critically, dietary genistein at concentrations that produced serum genistein levels substantially less than those in soy-fed infants produced marked thymic atrophy.

— These results raise the possibility that serum genistein concentrations found in soy-fed infants may be capable of producing thymic and immune abnormalities, as suggested by previous reports of immune impairments in soy-fed human infants.

References
Scientific Abstract from around the world
Continued

Page 71, (from the 132 page soy research paper)
- http://www.giftinfo.uni-mainz.de/EXCLI/volumes/Vol1/2002volume1pp8-14.pdf .

***EXCLI Journal* 2002;1:8-14 (ISSN 1611-2156), received: Dec 19, 2002, accepted Dec 29, 2002, published Dec 30, 2002.**

2002 "Dietary topoisomerase II-poisons: contribution of soy products to infant leukemia ?," – *Jan G. Hengstler, Carolin K. Heimerdinger and others*, Institute of Legal Medicine, Department of Molecular Toxicology, University of Leipzig, Johannisallee 28, 04103 Leipzig, Germany; Institute of Toxicology and Department of Gynecology, University of Mainz, Mainz, Germany

— DNA double strand breaks leading to chromosomal aberrations & leukemia's.
— Further studies on the role of dietary topoisomerase II-poisons are "urgently" required.

Page 49
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11980635&dopt=Abstract .

***Cancer Res* 2002 May 1;62(9):2474-7.**

2002 "Dietary genistein negates the inhibitory effect of tamoxifen on growth of estrogen-dependent human breast cancer (MCF-7) cells implanted in athymic mice," – *Ju Y.H. and others*, Department of Food Science and Human Nutrition, University of Illinois at Urbana-Champaign, Urbana, Illinois 61801, USA.

— Geistein overwhelmes the effects of Tamoxifen, Therefore Caution is warranted ...
--- Use of "dietary isoflavone supplements" by postmenopausal women "with breast cancer" is increasing.
— Dietary genistein negated or overwhelmed the inhibitor effect of tamoxifen on MCF-7 tumor growth, lowered E2 levels in plasma, and increased expression of E-response genes (e.g., pS2, PR, cyclin D1) in ovariectomized and athymic mice.
— "Therefore, **caution is warranted** for postmenopausal women consuming dietary genistein while on TAM therapy for E-responsive breast cancer."

Page 51
- http://www.soyonlineservice.co.nz/immune.htm,
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12032332&dopt=Abstract .

***Proc Natl Acad Sci* USA 2002 May 28;99(11):7616-21.**

2002 "The phytoestrogen genistein induces thymic and immune changes: a human health concern ?," – *Yellayka S. and others*, Department of Veterinary Biosciences, University of Illinois, Urbana, IL 61802, USA.

— Thymic & immune abnormality
— Genistein injections in ovariectomized adult mice produce dose-responsive decreased in **thymic** weight of up to 80%. Genistein decreased thymocyte numbers up to 86% and doubled apoptosis.
— There was a corresponding reduction in **splenic** cells.
— The does that caused significant thymic and immune changes in mice was comparable to those reported in soy-fed human infants.
— "These results raise the possibility that serum genistein concentrations found in soy-fed infants may be capable of producing thymic and immune abnormalities, as suggested by previous reports of immune impairments in soy-fed infants."
— http://www.mercola.com/2002/jun/8/soy.htm, **"Soy Weakens Your Immune System" ...**

— Dr. Mercola's Comment ... "It is quite amazing that this study was actually published, as the findings were quite negative for Soy, and yet it was funded by the United Soybean Board and the Illinois Council on Food and Agricultural Research ."

References
Scientific Abstract from around the world
Continued

Page 51, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11875621&dopt=Abstract .
***Arch Toxicol* 2002 Feb;76(1):23-9.**

2002 "Transplacental transfer of the phytoestrogen daidzein in DA/Han rats," – *Degen G.H. and others*, Institut fur Arbeitsphysiologie an der Universitat Dortmund, Ardeystrasse 67, 44139 Dortmund, Germany.

— **the placenta does not represent a barrier**

— The research found indications of **a rapid transfer of daidzen from the mother to the fetus**, but also that efficient extraction of daidzein from the maternal blood occurs. "Since dietary phytoestrogens account for a significant proportion of human exposure to potential endocrine modulators, and since the placenta does not represent a barrier to daidzein or related estrogenic isoflavones, the consequences of these exposures early in life should be examined and monitored carefully."

Page 52
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12113884&dopt=Abstract .
***J Soc Gynecol Investig* 2002 Jul-Aug;9(4)238-42.**

2002 "A pilot study of the effects of phytoestrogen supplementation on postmenopausal endometrium," – *Balk J.L. and others*, Department of Obstetrics, Gynecology, and Reproductive Sciences, Magee-Womens' Hospital, University of Pittsburgh, Pennsylvania 15213, USA.

— women ... hot flushes, night sweats, and vaginal dryness "did not" improve in the soy group.

— This was a double-blinded, randomized, placebo-controlled trial comparing the effects of 6 months of dietary phytoestrogen supplementation versus placebo in postmenopusal women.

— **"Phytoestrogens did not cause stimulation of the endometrium**. Insomnia was more frequent over the 6-month study in the soy group, where as - hot flushes, night sweats and vaginal dryness improved from baseline in the placebo group "but not" in the soy group."

Page 70
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12496060&dopt=Abstract .
***Cancer Epidemiol Biomarkers Prev.* 2002 *Dec;11(12):1674-7*.**

2002 "Dietary soy and increased risk of bladder cancer: the Singapore Chinese Health Study," – *Sun C.L., Yuan J.M., Arakawa K., and others*, USC/Norris Comprehensive Cancer Center, University of Southern California Keck School of Medicine, Los Angeles, California, USA., canlan@hsc.usc.edu .

— Bladder Cancer - (You can bet that the soy industry isn't promoting the results of this study !.)

— The Soyfood–bladder cancer risk association did not differ significantly between men and women and was not explained by other dietary factors.

— The Soy-cancer relationship became stronger when the analysis was restricted to subjects with longer (> or =3 years) duration of follow-up. To our knowledge, this is the FIRST epidemiological report on the effect of dietary Soy on bladder cancer risk.

References
Scientific Abstract from around the world
Continued

Page 70, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12089239&dopt=Abstract .

J Clin Oncol, Volume 20(13), July 1, 2002, 3040-3042.

2002 "Safety Issues of Soy Phytoestrogens in Breast Cancer Patients," - *de Lemos M.*, Vancouver, BC, Canada

— Risks versus Benefits ... breast cancer patients should be informed that phytoestrogens have the potential to stimulate tumor growth.

– http://www.jco.org/cgi/content/full/20/13/3040 ... **Safety Issues of Soy Phytoestrogens in Breast Cancer Patients**

Mário de Lemos
Vancouver, British Columbia, Canada
To the Editor:

— The results of Van Patten et al [1] confirmed previous findings [2] that soy phytoestrogens have minimal efficacy for menopausal symptoms in breast cancer patients. **However, I am concerned that patients in neither study were apparently informed of the potential stimulatory effects of phytoestrogens on breast tumor.** [3] Similar omission would have raised ethical concerns if pharmaceutical drugs were involved.

— At concentrations below 10 ? mol/L, phytoestrogens can stimulate breast tumor growth [4-15] and antagonize the antitumor effects of tamoxifen, [7,9] particularly in an environment of low endogenous estrogen.[3,11] In contrast, phytoestrogens inhibit breast tumor growth and enhance the antitumor effects of tamoxifen at concentrations above 10 ? mol/L. [5,6,8,9,11] In humans, serum phytoestrogen concentrations attained after acute or chronic intake of phytoestrogens were much lower than 10 ? mol/L. [1,16,17]

— Without long-term human data, cancer risk assessments need to be cautious and assume that substances that promote tumor growth in preclinical studies may pose similar risks clinically. [18] Hence, to weigh the potential risks versus benefits before using phytoestrogens for unproven indications, breast cancer patients should be informed that phytoestrogens have the potential to stimulate tumor growth.

Page 69
- http://www.soyonlineservice.co.nz/immune.htm,
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12520091&dopt=Abstract

***Mol Med* 2002 Nov;8(11):742-9.**

2002 "Early exposure to genistein exerts long-lasting effects on the endocrine and immune systems in rats," – *Klein S.L., Wisniewski A.B., Marson A.L., Glass G.E., Gearhart J.P.*, The W. Harry Feinstone Department of Molecular Microbiology and Immunology, The Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland 21205, USA.

— Discussion: These data illustrate that exposure to genistein during pregnancy and lactation exerts long-lasting effects on the endocrine and immune systems in adulthood. Whether exposure to phytoestrogens during early development affects responses to infectious or autoimmune diseases, as well as cancers, later in life requires investigation.

References
Scientific Abstract from around the world
Continued

Page 66, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12639286 .
J Med Food* 2001 *Spring;4(1):39-47

2001 "Effects of Genistein Isoflavone (4',5',7-Trihydroxyisoflavone) and Dexamethasone on Functional Characteristics of Spermatozoa," – *Kumi-Diaka J, Townsend J.*, *Florida Atlantic University, Department of Biological Sciences, College of Liberal Arts and Sciences, 2912 College Avenue, Davie, FL, 33314.*

— Genistein, alone or in combination with dxm, significantly interfered with percentage sperm motility and caused significant detachment of sperm heads

Page 43
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11297868&dopt=Abstract .
***Reprod Toxicol* 2001 Mar-Apr;15(2):105-10.**

2001 "Placental transfer of the soy isoflavone genistein following dietary and gavage administration to Sprague Dawley rats," – *Doerge D.R. and others*, Division of Biochemical Toxicology, National Center for Toxicological Research, U.S. FDA, Jefferson, AR 72079, USA.

— **Placental transfer to the foetal brain**
— Genistein was found to **"cross" - the rat placenta and reach the fetal brain** in doses similar to those observed in humans.

Page 44 and 67
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11573864&dopt=Abstract .
***Ann Pharmacother* 2001 *Sep;35(9):1118-21*,**

2001 "Effects of soy phytoestrogens genistein and daidzein on breast cancer growth," – *de Lemos M.L.*, *British Columbia Cancer Agency, Vancouver, BC, Canada.*

— Stimulate breast cancer growth !!. Yes !!.
— CONCLUSIONS: Genistein and daidzein may stimulate existing breast tumor growth and antagonize the effects of tamoxifen.
— Women with current or past breast cancer "should be aware of the "risks" of potential tumor growth" when taking soy products.

Page 65
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11714112&dopt=Abstract .
Cancer Causes & Control. 12(9):837-845, 2001 Nov.

2001 "Incidence of squamous neoplasia of the cervix and vagina in women exposed prenatally to diethylstilbestrol (United States)," – *Hatch EE. Herbst AL. Hoover RN. Noller KL. Adam E. Kaufman RH. And others.*, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, MD, USA.

--- Women exposed prenatally to diethylstibestrol **(DES)** have an excess risk of clear-cell adenocarcinoma of the vagina and cervix. The findings support an association between in-utero DES exposure and high-grade squamous neoplasia.

References
Scientific Abstract from around the world
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V
Page 47, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11431339&dopt=Abstract .

***Cancer Res* 2001 Jul 1;61(13):5045-50.**

2001 "Soy diets containing varying amounts of genistein stimulate growth of estrogen-dependent (MCF-7) tumors in a dose-dependent manner," – *Allred C.D., Yu Y.H., Virant S.M., and others*, Department of Food Science and Human Nutrition, University of Illinois, Urbana, Illinois, USA

---- Depending on processing, soy protein isolates, SPI's, vary widely in concentrations of genistein
— Cell proliferation was greatest in tumors of animals given estrogen or dietary genistein (150 and 300 ppm).
??? — Here we present new information that soy protein isolates containing increasing concentrations of genistein stimulate the growth of estrogen-dependent breast cancer cells in vivo in a dose-dependent manner.

Page 47
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11577007&dopt=Abstract .

***Carcinogenesis* 2001 Oct;22(10):1667-73.**

2001 "Dietary genistin stimulates growth of estrogen-dependent breast cancer tumors similar to that observed with genistein," – *Allred C.D. Chang J.,and others*, Department of Food Science and Human Nutrition and Division of Nutritional Sciences, University of Illinois, at Urbana-Champaign, IL 61801, USA.

— Genistin, the glycoside form of genistein, is converted to genistein by human saliva.
— The glycoside genistin, like the aglycone genistein, can stimulate estrogen-dependent breast cancer cell growth in vivo.
— Removal of genistin or genistein from the diet caused tumors to regress.

Page 67
- http://www.eurekalert.org/pub_releases/2001-11%20uoia-efi110101.php , and ...
- http://www.headliner.nl/headliner.php?c=us&abbr=eurekalert&id=187 , and ...
- http://search.eurekalert.org/e3/query.html?col=ev3rel&qc=ev3rel&qt=estrogen+found+in+soy+stimulates+human+breast-cancer+cells&x=21&y=6 .

J Nutr - (Nov.), Carcinogenesis - (Oct.), Cancer Res - (July), 3 studies funded by National Institute of Health, an ElurekAlert Press Release., Nov 1, 2001.

2001 "Estrogen found in soy stimulates human breast-cancer cells in mice," – *William G. Helferich*, University of Illinois, USA

— "Caution is warranted ... for women with breast cancer"
— The findings in **3 studies** found that genistein in various forms stimulates tumor growth.
— They also suggest that women with estrogen-dependent brest cancer or predisposition to it may want to reduce their consumption of soy products with a high isoflavone content.
— In the paper in Carcinogenesis, the researchers compared the isoflavone in its two forms, as a glycoside (genistin, as it appears in plants) and aglucone (genistein). They found that both forms produced similar tumor growth rates, and that the conversion of genistin in the body begins with contact with saliva in the mouth.
— In Cancer Research, Helferich compared soy protein isolates containing varying levels of isoflavones.
— The researchers found that estrogen-dependent tumor growth increases as the isoflavone content increased in the soy-containing diet.
— Researchers used athymic mice that lacked the ability to reject human cancer cells.

References
Scientific Abstract from around the world
Continued

Page 43, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11738518&dopt=Abstract .
***Reprod Toxicol* 2001 Nov;15(6):647-63.**

2001 "Effects of dietary genistein exposure during development on male and female DC (Sprague-Dawley) rats," – *Declos K.B., Bucci T.J., Lomax L.G. Latendresse J.R., and others*, Division of Biochemical Toxicology, NCTR, Jefferson, AR, USA. bdelclos@nctr.fda.gov

— Genistein is a naturally occurring isoflavone that interacts with estrogen receptors and multiple other molecular targets.
— Human exposure to genistein is predominantly through consumption of soy products, including soy-based infant formula and dietary supplements.
— A dose range-finding study was conducted as a prelude to a multigeneration bioassay to assess potential toxicities associated with genistein consumption.
— "Dietary genistein thus produced effects in multiple estrogen-sensitive tissues in males and females that are generally consistent with its estrogenic activity.
— These effects occurred - within - exposure ranges achievable in humans."

Page 46 and 65
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11250801&dopt=Abstract .
Environ Health Perspect 2001 Mar;109 Suppl 1:5-20.

2001 "Cross-species and interassay comparisons of phytoestrogen action," – *Whitten P.L., Patisaul H.B.*, *Department of Anthropology, Emory University, Atlanta, Georgia 03022*, USA.

Humans are affected at lower doses than rodents.

— "In vivo data show that phytoestrogens have a wide range of biologic effects at doses and plasma concentrations seen with normal human diets. Significant in vivoresponses have been observed in animal and human tests for ... bone ... breast ... ovary ... pituitary ... vasculature ... prostate ... and serum lipids."
— The doses reported to be biologically active in humans (0.4--10 mg/kg body weight/day) are lower than the doses generally reported to be active in rodents (10--100 mg/kg body weight/day), although some studies have reported rodent responses at lower doses.
— However, available estimates of bioavailability and peak plasma levels in rodents and humans are more similar. Steroidogenesis and the hypothalamic-pituitary-gonadal axis appear to be important loci of phytoestrogen actions, but these inferences must be tentative because good dose-response data are not available for many end points.
— The similarity of reported proliferative and antiproliferative doses illustrates the need for fuller examination of dose-response relationships and multiple end points in assessing phytoestrogen actions.

Page 43
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11389053&dopt=Abstract .
***Cancer Res* 2001 Jun 1;61(11):4325-8.**

2001 "Uterine adenocarcinoma in mice treated neonatally with genistein," – *Newbold R.R., Banks E.P., Bullock B., and others*, Developmental Endocrinology Section, Laboratory of Toxicology, Environmental Toxicology Program, Division of Intramural Research, National Institute of Environmental Health Sciences, Research Triangle Park, NC, USA.

— Genistein in soy was found to be more carcinogenic than DES, especially during "critical periods of differentiation ... the use of soy-based infant formulas in the absence of medical necessity and the marketing of soy products designed to appeal to children should be closely examined."

References
Scientific Abstract from around the world
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Page 66, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=11335767 .
Pediatrics.* 2001 *Apr;107(4):E45.

2001 "Severe nutritional deficiencies in toddlers resulting from health food milk alternatives," – *Carvalho NF, Kenney RD, Carrington PH, Hall DE.*, *Scottish Rite Pediatric and Adolescent Consultants, Childrens Healthcare of Atlanta, Atlanta, Georgia 30342-1600, USA*. drnorm@aol.com

Malnutrition ... from ... False nutritional beliefs.

Infants on Soy milk and Rice milk with severe nutritional deficiencies

— It is widely appreciated that health food beverages are not appropriate for infants. Because of continued growth, children beyond infancy remain susceptible to nutritional disorders. We report on 2 cases of severe nutritional deficiency caused by consumption of health food beverages. In both cases, the parents were well-educated, appeared conscientious, and their children received regular medical care. Diagnoses were delayed by a low index of suspicion. Because nutritional deficiencies are uncommon in the United States, US physicians may be unfamiliar with their clinical features.

*** Case 1.)** 22-month-old male child, with a history of chronic eczema and perceived milk intolerance, he was started on a rice beverage after weaning. Observed typical features of kwashiorkor: generalized œdema, hyperpigmented and hypopigmented skin lesions, abdominal distention, irritability, and thin, sparse hair. kwashiorkor impairs cellular immune defenses and electrolyte imbalances with ongoing diarrhea.

**** Case 2.)** a 17-month-old black male, Growth and height arrest after 9 months on soy milk.

— Reported regression in gross motor milestones, patient was unable to crawl or roll over.

— Generalized hypotonia, weakness, and decreased muscle bulk were present.

— Was diagnosed with rickets. Clinical features of rickets present on examination included: frontal bossing, an obvious rachitic rosary (photographed), genu varus, flaring of the wrists, and lumbar kyphoscoliosis. The published radiographs are diagnostic of advanced rickets, showing diffuse osteopenia, frayed metaphyses, widened epiphyseal plates, and a pathologic fracture of the ulna.

— The serum alkaline phosphatase and parathyroid hormone level was markedly elevated . Phosphorus was low, calcium was low normal , the 25-hydroxy-vitamin D level was low

Page 44
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12132873&dopt=Abstract .
***Cancer Detect Prev* 2001;25(6):527-32.**

2001 "Effects of the dietary phytoestrogens daidzein and genistein on the incidence of vulvar carcinomas in 129/J mice," – *Thigpen J.E. and others*, Comparative Medicine Branch, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina 27709, USA

— Within one month, the incidence of vulvar **carcinomas** in mice fed a modified soy protein diet was significantly increased over those of mice fed control diets.

— Within 3 months, the incidence of vulvar **carcinomas** in mice fed the soy protein diet was significantly increased over those of mice fed other control diets.

— "We concluded that dietary levels of daidzein and genistein were associated with an increase in the incidence of vulvar carcinomas in mice ... "

References
Scientific Abstract from around the world
Continued

Page 46, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11873863&dopt=Abstract .
***Endocr J* 2001 Dec;48(6):655-63.**

2001 "Neonatal exposure to genistein reduces expression of estrogen receptor alpha and androgen receptor in testes of adult mice," – *Shibayama T. and others*, Core Research for Evolutional Science and Technology, Japan Science and Technology Corporation, Kawaguchi, Saitama.

— "Our results exhibited that the disruption of gene expression continued for long term such as ... **3 months after** administration of genistein ... even if no effect was found at conventional reproductive-toxicological levels. We have shown that neonatal administration of weak estrogenic compound (genistein) **affects male reproductive organs at molecular levels in adulthood**"

Page 44
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11694625&dopt=Abstract .
***J Nutr* 2001 Nov;131(11):2957-62.**

2001 "Physiological concentrations of dietary genistein dose-dependently stimulate growth of estrogen-dependent human breast cancer (MCF-7) tumors implanted in athymic nude mice," – *Ju Y.H. and others*, Department of Food Science and Human Nutrition, University of Illinois at Urbana-Champaign, Urbana, IL 61801, USA.

— Genistein stimulated breast tumor growth and cell proliferation in mice in a dose-responsive manner.

Page 42
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10917909&dopt=Abstract .
***J Nutr* 2000 Aug;130(8):1963-70.**

2000 "Mass Spectrometric determination of Genistein tissue distribution in diet-exposed Sprague-Dawley rats," – *Chang H.C., Churchwell M.I., Delclos K.B., and others*, Division of Biochemical Toxicology, National Center for Toxicological Research, Jefferson, AR 72079, USA.

— Genistein administered to mice via **maternal milk or fortified feed** showed dose-dependent increases in total **genistein concentration** in the **brain**, liver, mammary, ovary, prostate, testis , thyroid and uterus.

— Female liver contained the highest amount of genistein (7.3 pmol/mg tissue) and male whole brain contained the least (0.04 pmol/mg).

— These results for measured amounts of genistein, present as aglycone and conjugates, in putative target tissues provide a link with other studies in which blood concentrations and physiologic effects of genistein are measured.

Page 40
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10737721&dopt=Abstract .
***Cancer Lett* 2000 Feb 28;149(1-2):171-9.**

2000 "Influence of perinatal genistein exposure on the development of MNU-induced mammary carcinoma in female Sprague-Dawley rats," – *Yang J. Nakagawa H., and others*, Department of Pathology II, Kansai Medical University, Moriguchi, Osaka, Japan.

— ". . . perinatal genistein is an endocrine disrupter and increases the multiplicity of MNU-induced mammary carcinoma in rats."

References
Scientific Abstract from around the world
Continued

V
Page 40, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10762754&dopt=Abstract .
***Eur J Cancer* 2000 Apr;36(6):796-802.**

2000 "Genistein induces apoptosis and topoisomerase II-mediated DNA breakage in colon cancer cells," – *Salti G.I., Grewal S., Mehta R.R., Das Gupta T.K., and others*, University of Illinois at Chicago, College of Medicine, Department of Surgical Oncology, Chicago, USA

— **DNA breakage** in colon cancer cells occurred - **within 1 hour** - of treatment with genistein.

Page 39
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10425307&dopt=Abstract .
***Oncol Rep* 1999 Sep-Oct;6(5):1089-95.**

1999 "Maternal exposure to genistein during pregnancy increases carcinogen-induced mammary tumorigenesis in female rat offspring," – *Hilakiviv-Clarke L. Cho E. Onojafe I. Raygada M. and others*, Research Bldg., Lombardi Cancer Center, Georgetown University, NW, Washington, DC, USA.

— There is an increased breast tumor risk from foetal exposure to Soy ... Carcinogen-induced mammary tumorigenesis.

Page 38
- http://www.soyonlineservice.co.nz/immune.htm.
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10086720&dopt=Abstract .
***Leukemia* 1999 Mar;13(3)317-20.**

1999 "Infantile leukemia and soybeans–a hypothesis," – *Abe T.*,

— Genistein from soybeans contributes to **DNA strand breaks** and may be "largely responsible" for **infantile acute leukemia, (IAL).**

Page 37
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10207614&dopt=Abstract .
***Arch Toxicol* 1999 Feb;73(1):50-4.**

1999 "The phytoestrogens coumoestrol and genistein induce structural chromosomal aberrations in cultured human peripheral blood lymphocytes," – *Kulling S.E. Rosenberg B. and others*, Institute of Food Chemistry, University of Karlsruhe, Germany. Sabine.Kulling@chemie.uni-karlsruhe.de

— cause Chromosomal aberrations ... chromatid breaks ... gaps ... interchanges

References
Scientific Abstract from around the world
Continued

Page 35, (from the 132 page soy research paper)
. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10022277&dopt=Abstract .
Toxicol Lett. 1998 Dec 28;102-103:349-54.

1998 "Dietary phytoestrogens and their role in hormonally dependent disease," — *Strauss L., Santti R., Saarinen N., Streng T., Joshi S., Makela S.,* Institute of Biomedicine and Medicity Research Laboratory, University of Turku, Finland.

— Although epidemiological studies suggest that diets rich in phytoestrogens may be associated with low risk of breast and prostate cancer, **there is no direct evidence for the beneficial effects of phytoestrogens in humans.** It is plausible that phytoestrogens, as any exogenous hormonally active agent, might also cause adverse effects in the endocrine system.

— Epidemiological studies suggest that diets rich in phytoestrogens (plant estrogens), particularly soy and unrefined grain products, may be associated with low risk of breast and prostate cancer. It has also been proposed that dietary phytoestrogens could play a role in the prevention of other estrogen-related conditions, namely cardiovascular disease, menopausal symptoms and post-menopausal osteoporosis.

— However, there is no direct evidence for the beneficial effects of phytoestrogens in humans.

— All information is based on consumption of phytoestrogen-rich diets, and the causal relationship and the mechanisms of phytoestrogen action in humans still remain to be demonstrated.

— In addition, the possible adverse effects of phytoestrogens have not been evaluated.

— It is plausible that phytoestrogens, as any exogenous hormonally active agent, might also cause adverse effects in the endocrine system, i.e. act as endocrine disrupters.

Page 63
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9710315&dopt=Abstract .
Med Hypotheses* 1998 *Jun 50:6 457-64

1998 "Xenoestrogens significantly enhance risk for breast cancer during growth and adolescence," – *Ardies C.M. and Dees C.,* Department of Biological and Exercise Sciences, Northeastern Illinois University, Chicago 60625-4699, USA.

— Specifically, we hypothesize that during periods of high growth rates and during breast development the sensitivity of breast cells to estrogenic compounds is sufficiently great for xenoestrogens to significantly enhance risk for breast cancer.

— Breast cancer is one of the most common forms of cancer observed in women, and endogenous estrogen is thought to play a major role in its development.

— Because of this, any conditions or exposures which enhance estrogenic responses would result in an increased risk for breast cancer.

— The role of xenoestrogenic compounds, such as DDT, in the etiology of breast cancer is still very controversial. In the following paper we discuss recently-published observations by ourselves and others which indicate that xenoestrogens may play a significant role in the development of breast cancer.

References
Scientific Abstract from around the world
Continued

Page 36, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9729267&dopt=Abstract .

***Mutat Res* 1998 Aug 31;405(1):41-56.**

1998 "p53, mutations, and apoptosis in genistein-exposed human lymphoblastoid cells," – *Morris S.M. and others*, Division of Genetic and Reproductive Toxicology, National Center for Toxicological Research, Food and Drug Administration, Jefferson, AR 72079, USA

— cellular damage and *DEATH*, genistein in Soy is a chromosomal mutagen
— The phytoestrogen, genistein, is a naturally occurring isoflavone found in soy products.
— On a biochemical basis, genistein is a competitive inhibitor of tyrosine kinases and the DNA synthesis-related enzyme, topoisomerase-II (topo-II).
— Exposure of mammalian cells to genistein results in DNA damage that is similar to that induced by the topo-II inhibitor and chromosomal mutagen, m-amsa.

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Page 37
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9848512&dopt=Abstract .

***Am J Clin Nutr* 1998 Dec;68(6 Suppl):1431S-1435S.**

1998 "Effects of soy-protein supplementation on epithelial proliferation in the histologically normal human breast," – *McMichael-Phillips D.F. and others*, Depart. of Epithelial Biology, Paterson Institute for Cancer Research, Christie Hospital NHS Trust, Manchester, United Kindgom

— Soy foods stimulates breast proliferation ... after just 14 days
— Forty-eight women with benign or malignant breast disease were randomly assigned a normal diet either alone or with a 60 gram soy supplement containing 45 mg isoflavones, taken for 14 days.
— The proliferation rate of breast lobular epithelium ... significantly increased ... after just 14 days ... of soy supplementation ... when both the day of menstrual cycle & age of patient were accounted for. Thus short-term use of dietary soy containing isoflavone levels found in modern soy foods stimulates breast proliferation.
— Our results may be interpreted that genistein is a chromosomal mutagen and that p53 functional status affects the recovery of chromosomal mutants, possibly by signalling cells into the apoptosis pathways.

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Page 64
- http://www.soyonlineservice.co.nz/Refs/Helf.htm.
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=9848512 .

***Cancer Res* 1998 *Sep 1;58(17):3833-8., and Cancer Res* 1999 *Mar 15;59(6):1388*.**

1998 "Estrogenic effects of genistein on the growth of estrogen receptor-positive human breast cancer (MCF-7) cells in vitro and in vivo," – *Hsieh C.Y., Santell R.C., Haslam S.Z., Helferich W.G.*, Department of Food Science and Human Nutrition, Michigan State University, East Lansing 48824, USA.

— Proliferation of cultured human breast cancer cells ... Dees concluded that ' women should not consume particular foods, (eg. soy-derived products), to prevent breast cancer'.
— **IN SUMMARY**, genistein can act as an estrogen agonist in vivo and in vitro, resulting in the proliferation of cultured human breast cancer cells (MCF-7) and the induction of pS2 gene expression. Here we present new information that dietary genistein stimulates mammary gland growth and enhances the growth of MCF-7 cell tumors in ovariectomized athymic mice.
— **Dr Craig Dees** of Oak Ridge National Laboratory has also found that soy isoflavones cause breast cancer cells to grow.
— He reported that 'low concentrations of genistein may stimulate MC-7 cells to enter the cell cycle'. Dees concluded that ' women should not consume particular foods, (eg. soy-derived products), to prevent breast cancer'.

References
Scientific Abstract from around the world
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V
Page 33, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9168007&dopt=Abstract .
***Environ Health Perspect* 1997 Apr;105(Suppl 3):633-636.**

1997 "Dietary estrogens stimulate human breast cells to enter the cell cycle," – *Dees C. and others*, Health Sciences Research Division, Oak Ridge National Laboratory, Tennessee, USA

— Stimulates human breast cancer cells to enter the cell cycle

— Dietary estrogens were found to increase enzymatic activity leading to breast cancer. "Our findings are consistent with a conclusion that dietary estrogens at low concentrations do not act as antiestrogens, but act like DDT and estradiol to stimulate human breast cancer cells to enter the cell cycle.

Page 32
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9217716&dopt=Abstract .
***Lancet.* 1997 *Jul 5;350(9070):23-7.*,**

1997 Exposure of infants to phyto-oestrogens from soy-based infant formula, – *Setchell K.D., Zimmer-Nechemias L., Cai J., Heubi J.E.*, Clinical Mass Spectrometry Center, Children's Hospital Medical Center, Cincinnati, Ohio, 45229, USA.

— Soy has glycosides of genistein and daidzein or plant based chemicals that mimic estrogen

— The daily exposure of infants to isoflavones in soy infant-formulas is 6-11 fold higher on a body-weight basis than the dose that has hormonal effects in adults consuming soy foods.

— Circulating concentrations of isoflavones in the seven infants fed soy-based formula were 13000-22000 times higher than plasma oestradiol concentrations in early life, and may be sufficient to exert biological effects, whereas the contribution of isoflavones from breast-milk and cow-milk is negligible.

Page 34, (from the 132 page soy research paper, attachment)
***Food Chem Toxicol* 1997 Jun;35(6):605-13.**
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9225019&dopt=Abstract .

1997 "Induction of micronuclei, DNA strand breaks and HPRT mutations in cultured Chinese hamster V79 cells by the phytoestrogen coumoestrol," – *Kulling S.E. and Metzler M.*, Institute of Food Chemistry, University of Karlsruhe, Germany.

— Coumoestrol and genistein caused - DNA strand breaks - in cultured hamster cells.

Page 34
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9343831&dopt=Abstract .
***Nutr Cancer* 1997;28(3):236-47.**

1997 "Phytoestrogen concentration determines effects on DNA synthesis in human breast cancer cells," – *Wang C. and Kurzer M.S.*, Department of Food Science and Nutrition, University of Minnesota, St. Paul 55108, USA.

— **Stimulates** growth of tumors ... Suppress enzymes protective of breast cancer

— Soy intake caused larger mammary fat pad tumors to occur in mice.

— "Our data suggest the possibility that, at typical concentrations in humans, phytoestrogens and related flavonoids and lignans may **stimulate**, rather than inhibit, **growth of estrogen-dependent tumours**."

— Soy intake caused larger mammary fat pad tumors to occur in mice. **Soy feeding appeared to suppress enzymes protective of breast cancer.**

References
Scientific Abstract from around the world
Continued

Page 34, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9383784&dopt=Abstract .
***Nutr Cancer* 1997;29(1):48-54.**

1997 "Effects of dietary menhaden oil, soy, and a cyclooxygenase inhibitor on human breast cancer cell growth and metastasis in nude mice," – *Connolly J.M. and others*, Division of Nutrition and Endocrinology, American Health Foundation, Valhalla, NY 10595, USA.

— Phytoestrogens at levels close to probable levels in humans were found to stimulate cellular changes **leading to breast cancer**.

Page 34
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9249928&dopt=Abstract .
***Teratog Carcinog Mutagen* 1997;17(1):29-43.**

1997 "Effect of various genotoxins and reproductive toxins in human lymphocytes and sperm in the Comet assay," – *Anderson D. Dobrzynska M.M., Basaran N.*, Department of Genetic and Reproductive Toxicology, BIBRA International, Carshalton, Surrey, United Kingdom.

— DNA damage to human sperm ...
— "The integrity of DNA is necessary not only for the noncancerous state, but also for the accurate transmission of genetic material to the next generation."
— Human sperm exposed to the phytoestrogen **daidzein** had **reduced DNA integrity.**

Page 68
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=9064373 .
***Klin Padiatr.* 1996 *Nov-Dec;208(6):323-6.*,**

1996 Hypocalcemic tetany in 'alternative' soy milk nutrition in the first months of life, – *Anil M, Kiess W.*, *Abteilung Allgemeine Padiatrie und Neonatologie, Justus Liebig Universitat Giessen.*

Malnutrition ... from ... False nutritional beliefs.

— A 14 weeks old infant was admitted to the intensive care unit with life-threatening hypocalcemic-hyperphosphatemic spasms. Hypocalcemia-hyperphosphatemia was found to have been caused by feeding a high phosphate/ low calcium soy milk. The daily uptake of calcium was calculated to have been 3.3-6 mmol that of phosphate 30 mmol.
— The parents strongly believed that soy milk formulas were equivalent to breast milk and cow's milk formulas and lived on a strictly vegetarian diet. Therapy with calcium (at an initial dose of 2.25 mmol/kg/day) and 1.25 OH vitamin D3 (Rocaltrol, 0.25 microgram/day) normalized Ca, PO4, vitamin D and parathyroid hormone levels rapidly.
— Vegetarian feeding had led to life-threatening hypocalcemic hyperphosphatemic spasms in the infant.
— We conclude:. Vegetarian feeding had led to life-threatening hypocalcemic - hyperphosphatemic spasms in the infant, as well as, malnutrition and false nutritional beliefs have to be included as a potential cause of early hypocalcemia in infants.

References
Scientific Abstract from around the world
Continued

Page 33, (from the 132 page soy research paper)
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8896889&dopt=Abstract .

***Cancer Epidemiol Biomarkers Prev* 1996 Oct;5(10):785-794.**

1996 "Stimulatory influence of soy protein isolate on breast secretion in pre-and postmenopausal women," – *Petrakis N.L. Barnes S. and others*, Department of Epidemiology and Biostatistics, University of California, San Francisco 94143-0560, USA.

— Twenty-four, (24), normal pre- and postmenopausal white women, ages 30 - 58 were studied for one year.
— The authors noted that "the findings did not support our a priori hypothesis" that soy protected Asian women against breast cancer.
— "Instead, this pilot study indicates that "prolonged consumption" of soy protein isolate has a "stimulatory effect" on the premenopausal female breast ... genistein and daidzein in Soy protein isolate (SPI).

Page 31
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=7508622&dopt=Abstract .

***Prostate* 1994;24(2):67-78.**

1994 "Developmental estrogenization and prostatic neoplasia," – *Santti R. and others*, Department of Anatomy, University of Turku, Finland.

— Estrogens, more susceptible to prostate cancer later in life
— The association of estrogens with benign prostatic hyperplasia and prostatic cancer has been widely studied, but no conclusive evidence exists for a role of estrogens in prostatic disease. This paper reviews the literature and describes studies which have sought to show a correlation of estrogens and alterations in the prostates of humans and experimental animal models.
— Using the developmentally estrogenized mouse model, we propose an alternative role for estrogens as a predisposing factor for prostatic diseases: estrogen exposure during development may initiate cellular changes in the prostate which would require estrogens and/or androgens later in life for promotion to hyperplasia or neoplasia.
— Thus, the critical time for estrogen action would be during the development of the prostatic tissue.
— We further suggest that estrogen-sensitive cells may remain in the prostate and be more responsive to estrogens later in life or less responsive to the normal controlling mechanisms of prostatic growth.
— In other words, exposure of the developing male child to phytoestrogens in soy may make him more susceptible to prostate cancer later in life.

Page ... 30
- http://www.soyonlineservice.co.nz/immune.htm.
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8314908&dopt=Abstract .

***J Cell Sci* 1993 Apr;104 part4:961-73.**

1993 "Odd chromosome movement and inaccurate chromosome distribution in mitosis and meiosis after treatment with protein kinase inhibitors," – *Nicklas R.B. and others*, Department of Zoology, Duke University, Durham, NC 27706.

— Genistein, a protein kinase inhibitor, caused errors in "chromosome orientation" from grasshopper spermatocytes..

References
Scientific Abstract from around the world
Continued

Page 59, (from the 132 page soy research paper)
- http://www.soyonlineservice.co.nz/immune.htm.
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8242767&dopt=Abstract .

Cell Immunol* 1993 *Nov 152:(1) 271-8.

1993 "Induction of mouse thymocyte apoptosis by inhibitors of tyrosine kinases is associated with dephosphorylation of nuclear proteins," – *Azuma Y., Onishi Y., Sato Y., Kizaki H.*, Department of Biochemistry, Tokyo Dental College, Chiba, Japan.

— DNA fragmentation and cell *DEATH*

— Incubation of mouse thymocytes with the protein tyrosine kinase inhibitors herbimycin A and methyl-2,5-dihydroxycinnamate induced a decreased and altered profile of nuclear phosphotyrosine proteins in parallel with an increase in internucleosomal DNA fragmentation and cell death dose-dependently.

— No change in the profile of cytoplasmic phosphotyrosine proteins was observed. DNA fragmentation was dependent on the synthesis of RNA and protein, suggesting that the inhibition of tyrosine phosphorylation of the nuclear proteins induces apoptosis.

— DNA fragmentation was enhanced by simultaneous incubation with phorbol esters capable of activating protein kinase C.

— Genistein, another inhibitor of protein tyrosine kinase, induced DNA fragmentation more rapidly than herbimycin A, but there was no predominant alteration of phosphotyrosine proteins in early incubation, suggesting that genistein may induce apoptosis by a mechanism other than direct inhibition of protein tyrosinekinase activity.

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Page 29
- http://www.mercola.com/article/soy/avoid_soy.htm, **Foot Note #53.**

#53. Bulletin de L'Office Fédéral de la Santé Publique, no. 28, July 20, 1992.

1992 *"Bulletin de L'Office Federal de la Santé Publique,"* No 28, July 20, 1992.

— The Swiss Health Service estimates that **100 grams of soy protein** provides the estrogenic equivalent of the **contraceptive pill.**

Page 29
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=1387742&dopt=Abstract .

***Toxicology* 1992;72:135-149.**

1992 "Validation of Two In Vitro Test Systems of Estrogenic Activities with Zearelenone Phytoestrogens and Cereal Extracts," – *Mayr U., Butsch A.*, Institut fur Tierernahrung, Universitat Hohenheim, Stuttgart, Germany.

— disease ... in all kinds of farm animals ... inherent health risk ... to man cannot be excluded.

— "Ingestion of these compounds causes diseases of the ... reproductive system ... reversible and irreversible infertility ... and abnormal fetal development ... **in all kinds of farm animals**.

— Furthermore, an inherent health risk to man cannot be excluded." This paper contains graphs showing the crossover of phytoestrogens from estrogenic to antiestrogenic to toxic.

References
Scientific Abstract from around the world
Continued

Page 29
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=1330289&dopt=Abstract .
***Cancer Res* 1992 Nov 15;52(22):6200-8.**

1992 "Effects of genistein on the growth and cell cycle progression of normal human lymphocytes and human leukemic MOLT-4 and HL-60 cells," – *Traganos F., Ardelt B., and others*, Cancer Research Institute, New York Medical College, Valhalla 10595

— The results suggest that genistein "is exp ected to be a strong immuno-suppressant.
— Genistein (GEN) is an isoflavone known to inhibit both tyrosine protein kinases and DNA topoisomerase II.
— The effects of GEN on cell proliferation and cell cycle kinetics of human myelogenous leukemia HL-60 and lymphocytic leukemia MOLT-4 cell cultures were studied, and the data were compared to results obtained with normal human lymphocytes stimulated to proliferate with phytohemagglutinin.

Page 29.
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=1847252 .
***Transplantation* 1991 Feb;51(2):448-50.**

1991 "Evidence that genistein, a protein-tyrosine kinase inhibitor, inhibits CD28 monoclonal-antibody-stimulated human T cell proliferation," – *Atluru S., Atluru D.*, Department of Anatomy and Physiology, Kansas State University, Manhattan 66506

— Genistein blocks the production of T cells, needed for the immune system.
— The authors conclude: " ... that genistein is a powerful immuno-suppressive agent ..." and suggest that it has a potential use in the treatment of allograft rejection.

Page 28
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=2548712&dopt=Abstract .
***Cancer Res* 1989 Sep 15;49(18):5111-7.**

1989 "Inhibitory effects of the tyrosine kinase inhibitor genistein on mammalian DNA topoisomerase II," – *Markovits J., Linassier C., and others*, Laboratorie de Pharmacologie Moleculair, URA 158 du CNRS, U 140 de I'NSERM, Institute Gustave Roussy, Villejuif, France.

— Genistein stimulates double strand DNA breaks.
— Our results show that genistein (a) inhibits the decatenation activity of DNA topoisomerase II and (b) stimulates DNA topoisomerase II-mediated double strand breaks in pBR322 DNA on sites different from those of 4'-(9-acridinylamino)methanesulfon-m-anisidide, etoposide, and 2-methyl-9-hydroxyellipticinium.
— Finally, genistein treatment of DC-3F cells results in the occurrence of protein-linked DNA strand breaks as shown by DNA filter elution. Viscometric (lengthening) studies demonstrate that genistein isn't a DNA intercalator. Genistein is therefore an interesting compound because it induces cleavable complexes without intercalation.
— Taken together, our results show that genistein is an inhibitor of both protein tyrosine kinases and mammalian DNA topoisomerase II. This could be accounted for by the sharing of a common structure sequence between the two proteins at the ATP binding site.

References
Scientific Abstract from around the world
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Page 84
- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=2868833&dopt=Abstract .
Comp Biochem Physiol A.* 1986*;83(1):67-70

1986 "Effects of postnatal protein undernutrition on myelination in rat brain," – *Egwin P.O., Cho B.H., Kummerow F.A.,* Egwim PO, Cho BH, Kummerow FA.

— Damages the myelin to sheath around the nerves.

. — "A more pronounced retardation" in the initiation, progression and capacity of myelination in postnatal "Soy Protein under-nutrition was indicated."

— Pups were subjected, from birth, to - protein under-nutrition by feeding the lactating dams 8% casein (CS) or - 8% Soy Protein (SP) diet - up to weaning; the weanlings were fed the same diets until 6 weeks of age. At 3 and 6 weeks of age, **myelin was isolated from the brains and characterized**. The quantities of myelin and its content of cholesterol, galactolipids and phospholipids, were significantly depressed in the 8% CS and 8% SP groups but not when soy protein was fed at the same level as casein (25%) in the control. Furthermore, the severity of the deficits in myelination showed a differential pattern depending on the type of dietary protein fed. At weaning, the deficits with the 8% SP diet were 1.5-2.0-times greater than with the corresponding casein diet.

. — "A more pronounced retardation" in the initiation, progression and capacity of myelination in postnatal "Soy Protein under-nutrition was indicated."

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- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=2432794&dopt=Abstract .
Am J Pathol* 1986 *Dec; 125(3):620-4.

1986 "Effect of prenatal iron deficiency on myelination in rat pups," – *Yu G.S., Steinkirchner T.M. Rao G.A., Larkin E.C.,*

— Phytates in Soy are known to block iron absorption

— In this study, a histopathologic examination of the brain from iron-deficient or iron-supplemented rat pups was carried out. Pups were obtained from female rats, which were fed an iron-deficient or iron-supplemented diet during both pregnancy and lactation. Immediately after anesthesia and the collection of blood, pups were fixed by intracardiac infusion of 2% glutaraldehyde. Brain and cervical spinal cord were fixed, embedded in paraffin, and cut at 6-mu thickness. **Myelin was identified using Luxol fast blue stain.** As compared with controls (hematocrit, 30.8%), 11-day-old iron-deficient pups (hematocrit, 11.9%) showed reduced myelination in the spinal cord.

. — Although myelination increased somewhat in the iron-deficient 17-day-old pups (hematocrit, 8.5%), the amount of "myelin" in the spinal cord and white matter of cerebellar folds "was reduced" as compared with that of the corresponding controls.

— THESE OBSERVATIONS SHOW - the importance of prenatal iron adequacy in myelinogenesis.
(The unborn child also gets what the mother eats. Here is another good reason to avoid Soy in pregnancy.)

So to try and bend the scientific evidence to try to make it fit what the soy industry and the pharmaceutical companies want it to look like, that soy supposedly prevents cancer, is doing the same thing the pharmaceutical companies did for over 20 years before June 2002, when the studies on Hormone Replacement Therapy, HRT, were stopped because these studies were proving that HRT was causing the very illness in women, including cancer, that the pharmaceutical companies were claiming and saying that HRT prevented. This is what we feel can be called crimes against humanity in the extreme. Soy being used as a weapon of mass destruction, devastation, unimaginable pain and suffering, heart ache and death !!.

References
Scientific Abstract from around the world
Continued

- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=7192012 .
Scandinavian Journal of Gastroenterology*, 1980*; 15(4):497-502

1980 "The effects of long-term feeding of soya flour on the rat pancreas," — *McGuinness E.E., Morgan R.G., Levison D.A. and others*

— Pancreatic cancer
— Rats were fed raw and heated soya flour for up to 2 years.
— The rats fed raw soya flour all developed pancreatic hypertrophy and hyperplastic and adenomatous nodules. Four of 26 rats fed raw soya flour continuously and 1 of 5 rats fed raw soya flour for 2 days each week developed pancreatic cancer.
— Preheating the soya flour seemed to protect against the pancreatic hyperplastic and neoplastic changes.
— But long periods of heat and pressure also required (130 degrees Celsius) to deactivate the carcinogenic trypsin inhibitors in soya flour denatures the soy proteins to the point that they become virtually useless.
— Then one either chooses less heating, resulting in more surviving trypsin inhibitors, or more heating, resulting in useless protein. **William Jarvis, Ph.D.,** Department of Health Promotion and Education, **Loma Linda University**, Loma Linda, California, USA.

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- http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=570914&dopt=Abstract .
***Endocrinology* 1978 Nov;103(5):1860-7.**

1978 "Phytoestrogen interaction with estrogen receptors in human breast cancer cells," – *Martin M.P., Horwitz K.B., and others*,

— Phytoestrogens can markedly enhance tumor cell proliferation. The interactions of phytoestrogens with estrogen receptors were studied in the human breast cancer cell line, MCF-7.
— The compounds tested were ... coumestrol ... genistein ... and formononetin and the mycotoxins, zearalenone and its reduced derivative, zearalenol. All but formononetin compete for binding of [3H]-estradiol to unfilled cytoplasmic estrogen receptor or unfilled nuclear estrogen receptor sites.
— The phytoestrogens are also biologically active; they can markedly enhance tumor cell proliferation.
— In summary ... phytoestrogens interact with the estrogen receptors of human breast cancer cells in culture and, therefore, may affect estrogen-mediated events in these cells.

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These 61 abstracts are only some, out of hundreds available in NCBI PubMed, from the continually growing body of scientific research on the many "health hazards" of eating soy, of putting soy in our food supply. With the scientific evidence that follow, think about all of these known and ignored "side-effects" listed here. Now, you can begin to start counting the number of people, worldwide, likely to be seriously hurt and/or dying from eating soy simply because of what these people were told, were tricked into believing, were lied to, most of the time deliberately, with misinformation, which "persuaded" them to believe, persuaded to trust, to have false hope, by the soy industry and their supporters, world wide, which goes something like this ... "Trust us, using soy is going to help (you)them, even help save (your)their life" ... when in reality, soy is slowly and "violently killing them".

More at Soy Online Service ... http://www.soyonlineservice.co.nz/, and W.A.P.F ... http://www.westonaprice.org/splash_2.htm.

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